Nutraceuticals / Functional Foods

An Exploratory Survey on Canada's Potential

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for

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The information in this report is based on opinions expressed by survey respondents, articles published by non-government sources, and interpretations of a contracted researcher. The views expressed herein do not necessarily represent those of Agriculture and Agri-Food Canada or the government of Canada.

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Executive Summary

Introduction

A nutraceutical is any food or food ingredient considered to provide medical or health benefits, including the prevention and treatment of disease. (28) The market for nutraceuticals is growing quickly worldwide, and it is this global scope that particularly attracts marketers. (49a) It is estimated that $250 billion, 50% of the U.S. food market of $503 billion, may be attributable to nutraceutical use if taken at its broadest definition (dietary supplements, sugar substitutes, fat substitutes, fiber-enriched foods, vegetables, fatless meat, skim milk, low-calorie diets, etc.). (28) Demand from the larger European population would bring that figure up to $500 billion. (28) Nutraceutical products are emerging in several European countries, and this has led the European Commission to pursue a common set of rules for the EU. (49a) Nutraceuticals constitute a $4 billion market in Japan, and play a major role in that country's health revolution. (29) Functional beverages are already a developed market in Japan. Schwepps, for example, is marketing a vitamin C-enhanced cola there. (49b) It is predicted that the gate will open for food and pharmaceutical companies' nutraceutical products in the U.S. market, mainly because of demographic and health-care trends. (49a) Both the food and pharmaceutical industries are interested in and aggressively developing this product category.

Little is known about the nutraceutical industry in Canada, yet this sector has the potential to grow and capitalize on tremendous global marketing opportunities. It is thus important to characterize the industry as it exists in Canada now, and identify what it needs to help it take advantage of the growing market for nutraceuticals, both as final products and as food ingredients, around the world. The Market and Industry Services Branch of Agriculture and Agri-Food Canada thus commissioned Food Focus to carry out this research.

Objectives

The objectives of this research were to define and describe the strengths, weaknesses and opportunities of the nutraceutical sector and market in Canada and identify the perceived needs of the Canadian industry for it to grow and realize its potential in domestic and foreign markets. Specific kinds of information to be obtained included the types of ingredients and value-added products already being produced and marketed; those with the potential to be produced and marketed; incentives and barriers to success; the type and amount of government support required to help enhance the recognition, vitality and competitiveness of the industry on an international basis; and future action steps on the part of both industry and government.

Methodology

One-hour interviews were carried out with 52 individuals representing 45 companies and organizations in the Canadian nutraceutical community. The interviews were conducted in person in Toronto and Guelph, and by telephone for the British Columbia, Prairie and Atlantic regions. Included in the sample were representatives of nine ingredient manufacturers/suppliers, eight food and three pharmaceutical manufacturers, three herb processors, two dairy companies,

two egg processors, a vitamin manufacturer, a wine manufacturer, a beverage manufacturer, a product developer, seven academic researchers, three government research and development centers, a food trade association, a regulatory affairs consultant, an agri-food public relations expert, and a medical reporter/physician. Interviewees were selected on the basis of familiarity with nutraceuticals, functional foods or ingredients, and on previous interest shown or initiatives taken in the field.

This was intended to be a qualitative study and the 54 interview questions were almost entirely open-ended.

Results and Discussion

Definition of the nutraceutical concept in Canadian terms and the criteria for a term which represents the nutraceutical industry in Canada

Respondents recognized a nutraceutical as "a food or food ingredient which has health benefits, including the prevention and treatment of disease." Nutraceuticals were regarded as a business opportunity, economic opportunity (health care-cost savings), and quality-of-life opportunity.

Most respondents believed the appropriate place for nutraceuticals is in the prevention of disease and that this is the focus of most of the research and development in Canada.

The majority knew of more than one word to describe the category. The most commonly used terms were thought to be nutraceuticals and functional foods. Few respondents really liked these words for describing foods with health claims and indicated they would prefer a term that connotes better the role of nutraceuticals in modulating risk factors and preventing disease; however, there was no consensus on a new term.

Identification of the most pertinent as well as strongest industries, i.e., food and pharmaceutical

Respondents indicated there are nutraceutical-related activities going on equally in the manufacturing and the ingredient sectors of the food industry. The identification and extraction of biologically available ingredients of either animal or vegetable origin appear to be the key to the development of the nutraceutical concept in Canada. The food ingredient sector is leading in this area. The food manufacturing industry plays an integral role, having the ability to formulate palatable foods, while protecting the bioavailability of the nutraceutical ingredient(s).

Degree of, potential for, and corporate profile of food and pharmaceutical companies which will interact and cause the nutraceutical industry to evolve

In total, 36 companies could identify the strategy by which they came to be involved in nutraceuticals. They were found to be using either of two approaches. The first is market-opportunity driven, whereby they are scanning literature and listening to consumers and health professionals. They recognize an opportunity to add value to their business by targeting a public health issue or fulfilling a consumer need. The second approach is value-added driven, whereby companies research their products, then seek market segments that will benefit from the attributes of these new products.

Strategic alliances are being or have been formed among food ingredient specialists, food manufacturers and academic researchers. These companies recognize their relative strengths and weaknesses and partner to either maximize or overcome them. While any combination of strategic partnerships is possible, the most common denominators seemed to be a key ingredient supplier and a source of independent nutrition research. Most alliances were found to be at an exploratory stage.

The ideal alliance was seen to include: credible, high quality food processors; independent, scientifically credible researchers; the federal government; leading biotechnology and pharmaceutical support.

Types of products currently produced and marketed

At least 65 current nutraceutical products were named. The range was very broad and included a multitude of agri-food ingredients native to Canada. Among them were nutrients from both animal and vegetable sources, such as amino acids, fats, dietary fibers, plant pigments, animal pigments, antioxidants, vitamins and minerals.

Types of products with nutraceutical potential

Comments from the respondents illustrate the perceived potential range of nutraceuticals in Canada:

- "limitless, the gamut of the kitchen table"
- "all foods are potential candidates"
- "all agricultural products have potential"
- "anything which can be produced in Western Canada, but development requires joint venturing"
- "many, and they're all ag biotech based."

Sixteen respondents named approximately 40 potential nutraceuticals they are currently researching or intend to research in the future. These products tended to be a natural outgrowth of a company's existing expertise and resources, differing little from its regular line of products. From dairy processors, herbalists and cereal chemists, to marine oil specialists, companies said they build upon past successes and present strengths, pursuing product extensions of their base business.

These companies appeared to prefer to offer new products to consumers in familiar foreign and domestic markets, rather than seek new markets.

State of market readiness—domestic

Three factors that determine market readiness were considered: consumer awareness/acceptance; industry awareness/responsiveness; and government legislative support/endorsement.

The majority of respondents (28, or 60%) believed that Canadian consumers are aware, or are becoming increasingly aware of the nutraceutical potential in food. They confirmed their answers by citing published surveys. Most of the survey participants also believed that there are health benefits associated with the nutraceutical products they mentioned, and that these have

been sufficiently well proven or established. However, it seemed that, in many cases, the substantiating evidence required to comply with the *Food and Drugs Act and Regulations* is lacking. The inability to have these health benefits officially recognized domestically is considered to be delaying market growth and stalling market readiness, despite consumer belief in the health benefits of food. According to the respondents, lack of official sanction is due to four factors: inadequately defined and unstandardized scientific protocol, scientific discord, lack of legislative support, and the cost of and lack of funding for clinical trials. It may be that the cost of clinical trials is the bottleneck to the resolution of the first three barriers.

Currently dissemination of information through indirect promotional campaigns is the primary method of promoting nutraceutical benefits to Canadians. The media utilized may or may not involve the medical and health-care community. If so, there is implied endorsement on the part of the health-care professional. The technical data supporting the implied benefit must accompany the message. This indirect method was regarded by respondents as inefficient, expensive and, in some cases, fraudulent. However, it is employed because of: the fundamental belief that Canadians associate particular foods with health benefits; the manufacturers' belief in the health benefits; and the fact that *Food and Drugs Act and Regulations* prohibits direct claims.

There was consensus among the respondents that raising consumer awareness of the health benefits of particular foods would require a supportive regulatory framework and consensus among nutritionists and researchers with respect to health claims on food. Without both, it was felt that consumers will remain confused because of poorly communicated, yet, perhaps, justified health claims. Respondents indicated that the awareness-raising effort should be comprised of a multisectoral strategy involving all levels of government, public health professionals, educational institutions, and the medical community.

A large majority of respondents saw grocery stores as the most appropriate distribution channel for nutraceuticals. Citing accessibility, mass-market pricing, conveyance of the product as a food, and consumer trialability many of these respondents not only spoke in support of grocery stores, but reasoned this choice in favor of other avenues, such as health food stores and pharmacies. Some respondents were not in favor of the pricing structure in drug stores and did not like the implied image of the nutraceutical as a drug.

Of those companies marketing nutraceuticals, none said they are doing so in Canada only. Companies with a major domestic focus tended to be branch plants of multinational food or pharmaceutical companies.

State of market readiness—international

Sixteen companies surveyed indicated they operate both in Canada and abroad. Seventeen said they are marketing internationally only. The latter tended to be smaller companies, either ingredient suppliers or food manufacturers. Determinants of market potential are supportive legislation, consumer awareness, volume potential, and past specific experience. The domestic market is smaller, has less volume potential and is less accessible than some foreign markets.

All those surveyed viewed international consumers as having an awareness of the benefits of nutraceuticals. The most markets most-often mentioned by respondents, in descending order, were Japan, the Pacific Rim, Asia, the U.S., Europe, Germany and Scandinavia. These tend to be

highly developed markets, in which consumers are very aware of nutraceuticals—the ability to make health claims, owing to either legislation or long-standing consumer acceptance based on cultural traditions and folklore, are factors that make them lucrative.

Claims are permitted in some countries but there varying requirements for substantiating them. The Canadian respondents seemed to know of the requirements for particular markets and whether they already have, or could acquire the necessary data to export products there. Overlooking cultural practices by simply providing supporting data for health-related claims will not ensure market success. It is necessary to position the active ingredient in food which is conducive with the eating patterns in host countries.

Key incentives for and dominant barriers to longevity, profitability and competitiveness

Consumers and their demand for quality of life are fueling the nutraceutical "revolution." Industry and research are attempting to meet this demand. Advanced technology and improvements in science may bring about a regulatory climate that allows for the health claims consumers are becoming more aware of and seem to be demanding more of.

Almost all respondents indicated that their company or industry can capitalize on growing consumer demand for nutraceuticals. Strategic alliances, niche marketing and a clear marketing strategy are the priority steps, as shown by the following requirements for success in the nutraceuticals market, which were cited most frequently by respondents in this survey:

1. form a strategic partnership with at least one other company;
2. niche market through entrepreneurship;
3. formulate, launch, claim, and deliver improved health;
4. target the $1.8 billion spent on health-care; change those expenditures to food expenditures;
5. adopt a clear marketing strategy with the right product; and
6. drop the "pharmaceutical" mentality.

Consumer awareness is almost a "given" in the international arena. Basic good business practices, international development, global travel, and consumers' increasing health consciousness leading to their exploration of alternative medicines and an inclination toward self-medication, will foster the nutraceutical revolution. Current exporters of nutraceutical products indicate a foreign market that is open and receptive to the goods and services Canadians have to offer. However, this can be either enhanced or hampered by lack of regulatory harmonization among countries.

Respondents indicated that to export, they need the assistance of the Department of Foreign Affairs and International Trade, as well as a host-country sponsor.

The Canadian *Food and Drugs Act and Regulations*, which prevents health claims on foods or in advertising, is seen as the major barrier to success in the Canadian nutraceutical market. Other barriers cited were related to marketing, product and research costs, and a lack of awareness among the public, industry and the medical profession.

Most respondents believed the current barriers can be overcome. Almost half believed there are no international barriers to nutraceutical market development, while the other half could specify at least one. Those with export experience were optimistic about opportunities for Canadian

nutraceuticals, citing the quality of Canadian standards and products as a strength to be built upon. They have acquired sensitivity and responsiveness to the host country's regulations, culture and eating patterns. Information and flexibility appear to be the keys to success.

International markets appear to be more accessible and foreign host government agencies more cooperative when developing a nutraceutical market than is true domestically. The accessibility of the foreign markets compensates for the cost of conducting business abroad. Government assistance in decreasing the length of the process was suggested.

The degree and type of government involvement and support necessary to help enhance the recognition, vitality and competitiveness of the industry on an international basis

Ninety percent (41) of the respondents believed government involvement is appropriate to grow both domestic and foreign markets for Canadian nutraceuticals. However, almost half could not think of any current beneficial federal government activities. This may be due, in-part, to negative experiences they may have had in the past, or to a lack of experience in working with government. Further, some of the respondents represented multinational corporations that tend not to require or seek the support needed by small companies. Those who did recount beneficial government activities, typically small entrepreneurs and research institutions, could do so because of experience acquired from working with government agencies.

The most commonly mentioned beneficial federal-government activities in support of a domestic nutraceutical market include:

- technological assistance
- funding of research
- loosening of the regulations (which occurred with the approval of Feverfew, fat substitutes, sugar substitutes)
- faster approval procedures (released by Treasury Board this year)

With respect to fostering an international nutraceutical market for Canadian products, respondents perceived it essential for the federal government to maintain a vibrant and credible department of foreign affairs.

A strong appeal was voiced for regulatory change that takes into account the role nutraceuticals could have in improving the health of Canadians and thus decreasing health-care costs, and for clear guidelines by which industry can abide. In addition, it was felt that the Canadian government should work with other stakeholders to develop a communication strategy for nutraceuticals.

Future action steps for both industry and government

There was a strong appeal made for a multisectoral approach to nutraceuticals in Canada.

The survey indicated that the most important strategic step would be for industry and the federal government to work together towards regulatory reform. The potential for nutraceuticals to decrease national health-care costs may provide an incentive to bring this about. Education and awareness-building to crystallize a market and help further research were also mentioned frequently by respondents as important activities. Government funding of and/or participation in

clinical research received numerous mentions as another important action step. It was also suggested that the research community should be selective in research projects, choosing those that meet the needs of Canadian consumers and industry and maximize the potential of Canadian agricultural crops; practice sound scientific research; promote achievements in the media; and develop centers of excellence in nutraceuticals research and development.

Conclusions and Recommendations

Stakeholders should recognize that Canadians and consumers in international markets are increasingly expecting health benefits from food. The growth in the size of the Asian population in Canada is not only influencing Canadian habits, but creating a diversified market. These factors are driving the nutraceuticals market.

Stakeholders should consider establishing a nutraceuticals (functional foods) advisory group or association composed of representatives from the food ingredient sector, food manufacturing sector, academic research community and, if possible, pharmaceutical sector to work with the federal government. A primary objective would be to bring regulatory agencies (food and drug) together to discuss the issues and options, and to determine what scientific information about nutraceutical products is required to bring about positive, realistic regulatory changes that would facilitate appropriate promotion and marketing of nutraceuticals based on their risk-management or disease-preventative attributes. Nutraceuticals might be positioned as an avenue for reducing escalating health-care costs; an illustration is Japan, where FOSHU was legislated to halt rising health care costs; although, it is, perhaps, too soon to know whether it has been successful in this regard. Another goal of the group could be to find ways of reducing the cost of clinical trials or ways in which the cost could be offset through government policies and programs. A third goal could be to facilitate and/or coordinate the development and implementation of a multisectoral communication strategy to build awareness with respect to the wide and interesting range of Canadian nutraceutical products, and the benefits they might offer in the area of disease prevention, risk-factor management, and enhancing the quality of life.

For research and development, stakeholders should target the mitigation of those chronic diseases that have the greatest impact on health care costs and emphasize those Canadian agri-food crops that have the strongest nutraceutical potential and commercial value in both domestic and international markets. It has been shown that investment is being made in research and development of nutraceuticals in Canada, and strategic alliances are being formed in the food ingredient sector, food manufacturing sector, and academic research community. An even greater emphasis on these activities by stakeholders and the agri-food network could lead to a greater return on investment through commercialization of more nutraceutical products, and sales of greater volumes of products in more markets.

Introduction

A nutraceutical is any food or food ingredient considered to provide medical or health benefits, including the prevention and treatment of disease. (28) Examples (49a) include:

- raw foods, such as carrots that contain beta carotene, which may reduce the risk of cancer;
- processed food without added ingredients, such as oat bran cereal, which may reduce serum cholesterol; and
- processed foods with added ingredients, such as calcium-enriched orange juice, which may reduce the risk of osteoporosis.

Another example might be a natural beta carotene extract added to foods, beverages and supplements. (29)

The market for nutraceuticals is growing quickly worldwide, and it is this global scope that particularly attracts marketers. (49a) It is estimated that $250 million, 50% of the U.S. food market of $503 billion, may be attributable to nutraceutical use if taken at its broadest definition (dietary supplements, sugar substitutes, fat substitutes, fiber-enriched foods, vegetables, fatless meat, skim milk, low-calorie diets, etc.). (28) Demand from the larger European population would bring that figure up to $500 billion. (28) Nutraceutical products are emerging in several European countries, and this has led the European Commission to pursue a common set of rules for the EU. (49a) Nutraceuticals" constitute a $4 billion market in Japan, and play a major role in that country's health revolution. (29) Functional beverages are already a developed market in Japan. Schwepps, for example, is marketing a vitamin C-enhanced cola there. (49b)

A U.S. survey (16) showed that both the food and pharmaceutical industries are interested in and aggressively developing this product category. Approximately 55% of food companies and 35% of pharmaceutical companies responding to the survey reported investing in nutraceuticals.

Nutraceuticals have gone far in the international market for a number of reasons: older demographics, national health care, cultures that value herbal and natural remedies, and an acceptance of the food to health relationship. (36) Those cultures also permit health claims, reimbursement is common and nutrition is part of the medical curriculum.

It is predicted that the gate will open for food and pharmaceuticals companies' nutraceutical products in the U.S. market, mainly because of demographic and health-care trends. (49a) Much has been written about functional and health properties of foods; however, it is clear that North American companies have not taken advantage of the commercial opportunities to the extent possible. While the results of new clinical trials are published daily and catch the attention of manufacturers in the food ingredient, food manufacturing, pharmaceutical, biotechnology and research communities, few of these findings are manifested into new food products with scientifically backed health claims.

Little is known about the nutraceutical industry in Canada and North America. Yet this sector has the potential to grow and capitalize on tremendous global marketing opportunities. It is thus important to characterize the industry as it exists in Canada now, and identify what it needs to help it take advantage of the growing market for nutraceuticals, both as final products and as

food ingredients, around the world. The Market Industry Services Branch of Agriculture and Agri-Food Canada thus commissioned Food Focus to carry out the research project reported on herein.

Highlights of Literature Review

1. A nutraceutical can be defined as any substance that may be considered a food or part of a food that provides medical or health benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, biotechnology products and dietary supplements to genetically engineered "designer" foods, herbal products and processed foods such as cereals, soups and beverages. (21)
2. The concept embodied in the term nutraceutical–the concept of disease control by diet–gained momentum in 1991 after the International Conference on Nutrition and Cancer in Atlanta, Georgia. (81)
3. A plethora of terms, used interchangeably with nutraceuticals and described by one (21) as "nomenclature chaos" has emerged. A representative of one prominent company in the industry has noted that every name has a different connotation. (38)
4. A number of nutrient-disease relationships have been observed. Some are based on clinical trials, some on epidemiological studies and some on anecdotal observations. Some of the potentially active nutrients/nutraceuticals cited in the literature include "designer foods" (12, 96), antioxidants (4, 6, 19), lignin (88), citrus limonoids (52), citrus compounds (60), citrus flavonoids (59, 72), pectin-fiber (1), Carotenoids (47, 75), tomatoes (where tomato juice was more effective than just the vitamin C component) (19), vegetables (2, 8, 75), broccoli sulforaphane (2), dairy products (37), and canola oil (71). Some researchers emphasized the role of the entire diet in not only maintaining health but disease prevention as well.
5. There were many appeals for regulatory controls on health claims from food. (16, 48, 93) There were also appeals for consistent, well-designed, and rigorously executed clinical trials. (12, 16, 30, 38, 39, 44, 47, 50, 65, 85, 97). This appeal for high scientific standards was more prevalent in the literature than that for regulatory control; however, the need for regulatory control is indeed recognized by the scientific community.
6. Japan leads in the area of legislated health claims on food; much can be learned from their approach. (13, 22, 35, 43, 45, 63, 79) As one industry professional put it, "Correlate the Asian success." (38)
7. In Canada health claims are not permitted on food. However, governments are facing an aging population and escalating health care costs. The recognition that a balanced diet could be a significant factor in the prevention of many diseases may influence the legislation to make it more supportive and flexible for marketers of nutraceuticals.
8. Two industries—the food industry and the pharmaceutical industry—are researching nutraceuticals; each has strengths to offer and weaknesses to be complemented. (5, 12, 16, 17, 22, 42, 55, 64) Representatives of both these industries are forming joint ventures and strategic alliances as they pursue the research, development and marketing of nutraceuticals.
9. A number of market barriers to nutraceuticals have been identified. The most commonly mentioned are the current regulatory climate (16, 64, 77, 86), the cost of clinical trials (16, 22, 65) and the apparent difficulty in obtaining patent protection (21, 23, 64, 77).

10. Market size remains nebulous. One author (69) writes, "We don't know the potential of the market and some of the estimates published differ significantly from each other." Without health claims, the U.S. (U.S.) market is predicted to grow slowly at 2.4% annually, to a total value of US $1.22 B in 1998; with health claims, the U.S. market is predicted to grow faster at 9% annually, to a total value of US $1.66 B in 1998. (14) With about 10% of the population of the U.S., the Canadian nutraceutical market in 1998 could range from US $100 M to US $160 M.
11. There are many determinants of success in the nutraceutical industry. (5, 16, 17, 23, 32, 41, 48,49a, 68, 73, 86, 95) The three forces likely to be the most significant appear to be escalating health care costs (closely tied in with a switch to nontraditional or alternative medicines), a growing awareness among consumers and physicians of the relationship between nutrient intake and health, and regulatory approval of health claims.
12. Strategic alliances and joint ventures are already in place, in particular between food and pharmaceutical companies. (17, 23, 64, 69)
13. Industry has conducted some consumer acceptance studies in relation to nutraceuticals. (32, 36, 83, 95, 96) In a U.S. study (95, 96), 30% of adults over the age of 18 considered themselves highly aware of the research activities linking disease prevention and naturally occurring substances in fruits, vegetables and cereal grains. Awareness increased with age.
14. One author (10) summarized many of the opportunities and issues raised in the literature: "Developing business in this area is not easy, but for those who approach the challenges with the right skills and resources, and have an integrated approach to development the commercial potential is considerable."

A more detailed literature review and bibliography are presented in Appendices 1 and 2, respectively.

Objectives

The primary objectives of this project were as follow:

1) To define and describe the nutraceutical market in Canada
   - Strengths
     - Types of products and ingredients already being produced and marketed successfully (e.g., value-added food products and ingredients with some health benefits)
     - Types of products and ingredients with the potential to be produced and marketed; incentives and barriers to success
   - Weaknesses
   - Opportunities
     - The extent to which Canada is ready to expand and take better advantage of international opportunities for nutraceuticals as food ingredients, and how this could be accelerated
2) To identify the perceived needs of the Canadian industry in order for it to grow, realize its potential, and identify and take advantage of market opportunities in domestic and foreign markets.
   - Opportunities, threats and barriers the industry will face

- Role for government: type and amount of support required, if any, to help enhance the recognition, vitality and competitiveness of the industry on an international basis
- Future action steps on the part of both industry and government

More specifically, the purpose was to define and describe the nutraceutical industry in Canada, considering the following key parameters:

1) definition of the nutraceutical concept in Canadian terms and the criteria for a term that effectively represents the nutraceutical industry in Canada;
2) identification of the most pertinent as well as strongest industries, i.e., food and pharmaceutical;
3) the most active sectors within those industries, i.e., ingredient suppliers, processors;
4) the degree of, potential for, and corporate profile of food and drug companies that will interact and cause the nutraceutical industry to evolve:
   - types of products currently produced and marketed,
   - types of products with nutraceutical potential,
   - state of market readiness —both domestically and internationally,
   - key incentives for and dominant barriers to longevity, profitability and competitiveness;
5) the degree and type of government involvement and support necessary to help enhance the recognition, vitality and competitiveness of the industry on an international basis; and
6) future action steps for both industry and government.

Methodology

One-hour interviews were carried out with 52 individuals representing 45 companies or organizations in the Canadian nutraceutical community. The interviews were conducted in person in Toronto and Guelph, and by telephone in the British Columbia, Prairie and Atlantic regions. Interviewees were selected on the basis of familiarity with nutraceuticals, functional foods or ingredients, and on previous interest shown or initiatives taken in the field. This was intended to be a qualitative study and the 54 interview questions were almost entirely open-ended.

Results

Description of respondents

The following table shows the number of respondents and the type of companies or organizations they represented. Twenty-one personal interviews (some involving more than one respondent) and twenty-four telephone interviews were completed for a total of 45 interviews, involving 52 individuals. The respondents were very vocal and enthusiastic about the subject of nutraceuticals.

Table 1. Number of respondents and type of company or organization represented

Sector	Number of companies	Number of individuals
Ingredient Manufacturer / Supplier	9	10
Food Manufacturer	8	11
Pharmaceutical Manufacturer	3	3
Herb Processor	3	4
Dairy Manufacturer	2	2
Egg Processor	2	2
Vitamin Manufacturer	1	1
Wine Manufacturer	1	1
Beverage Manufacturer	1	1
Product Developer	1	2
Academic Research	7	7
Government R&D Center	3	3
Food Trade Association	1	1
Regulatory Affairs Consultant	1	1
Agri-Food Public Relations	1	1
Medical Reporter / Physician	1	2
Total	45	52

Responses

Company nutraceutical perspective

1. What does "nutraceutical" mean to your company?

Almost one-third (14) of the respondents answered with the word "opportunity" and by either defining the type of opportunity or justifying it. Examples of the type of supporting statements include:

- an opportunity because nutrients can modify physiological processes
- an opportunity so huge that some people just back away from it
- an opportunity for the food industry to grow; to look at food as a solution to health problems; to reduce health care costs; to improve quality of life
- a significant opportunity to upgrade the image of existing products; to introduce new products; to allow the food industry to comply with the objectives of the Nutrition Recommendations for Canadians
- we're looking at the bottom line. By increasing the source of nutrients in what you have you can help the nation as a whole by reducing health-care costs
- an opportunity that remains ill-defined

Almost half, or 23 of the respondents provided a definition for the word "nutraceutical" in response to this question. Some answers were very simple, others quite complex. A few examples illustrating the range of definitions provided are as follow:

- an edible product containing natural functional constituents (nutrients or non-nutrients) which, when consumed, are safe and have been scientifically proven in human studies to provide a significant demonstrated health benefit for disease management including selective risk factors
- a food which has specific physiological or medicinal benefits when consumed in normal amounts; this could also be an extracted ingredient put into a food.
- nutritional products with medicinal qualities, either therapeutic or prophylactic, e.g., beta carotene
- a chemical that has potential health benefits: [It] is not clearly defined; if so, it would be a pharmaceutical
- a nutritional plus pharmaceutical application based on health studies, clinical research and science, which isolates key active ingredients within foods that would be beneficial
- something which is nutritional, healthful
- a food product which has pharmaceutical value
- foods that are good for you

Slightly under one-quarter of the respondents provided general answers related to both the opportunities offered by nutraceuticals and the definition of a nutraceutical, such as:

- the future of real diet therapy, as there is a big future in the prevention of disease
- a big challenge to respond to a big demand

The food industry has drawn a link between the foods it produces and the potential health benefits these foods may offer. This link is regarded as a business opportunity, an economic opportunity (health care-cost savings) and a quality-of-life opportunity.

There were few statements of caution or limitation to balance the expressions of opportunity, indicating a fair degree of optimism.

Industry dynamics

2. How would you classify the industry in which your company's nutraceutical R&D activity takes place? (food ingredient processing, food manufacturing, pharmaceutical, biotechnology.....)

food ingredient suppliers or processors	12
food manufacturing/processing	11
all of the above	4
biotechnology	4
food manufacturing and pharmaceutical	4
pharmaceutical	3
food and food supplement manufacturing	1
food processing, pharmaceutical, biotechnology	1
none of these; it's new; nutraceutical	1
food processing plus biotech	1
Can't say.	3

Respondents said there are nutraceutical-related activities going on in equal amounts in both the manufacturing and ingredient sectors of the food industry. A few cited biotechnology as the means by which ingredients can be isolated and examined for use by the food manufacturing industry. Others cited the pharmaceutical industry as having this extraction expertise, the results of which can then be utilized by the food manufacturing industry. In any case, the food industry and not the pharmaceutical industry, was seen as the major player. In contrast, the literature reviewed positioned the pharmaceutical industry as playing a role equal to that of the food industry. The reasons for this difference may be as follow:

- The literature was largely American, where pharmaceutical companies have large research laboratories and facilities. Canadian pharmaceutical companies do not typically have the same research resources, and thus, cannot play an equally active role in Canada as they do in the U.S.
- A related fact, is that "Most active ingredients in pharmaceuticals sold in Canada are imported." (Pharmaceuticals Industry, Science and Technology Canada Industry Profile. 1992, p. 2). This concurs with the first reason. A Canadian branch plant may not be free to develop a nutraceutical which would compete with/cannibalize the parent company's export revenue from active ingredients.
- Three researchers believed that all pharmaceutical companies are involved, but are working behind closed doors.

It should be noted that there were only three pharmaceutical companies included in this survey, and it may be that those companies did not want to share information regarding their alliances or research for instance. As most of their research is likely to be done abroad maybe Canadian respondents were not fully aware of these activities.

The fact that most pharmaceutically active ingredients in Canada are imported indicates an opportunity for Canada to develop a domestic nutraceutical market which does not directly compete with domestically-developed value-added active ingredients. Conceivably, a healthy domestic nutraceutical market could cause a decrease in the amount of pharmaceutically active ingredients imported, resulting in a net value-added gain for Canada.

3. Which sector(s) of this industry is most active/pro-active? (processors, ingredient suppliers...)

♦ ingredient suppliers	18
♦ food manufacturing	10
♦ pharmaceutical	3
♦ food ingredient plus food manufacturing	2
♦ biotechnology	2
♦ No one is pro-active at this point.	2
♦ ingredient suppliers plus biotechnology	1
♦ All sectors are equally involved.	1
♦ Can't say.	6

The majority of respondents, about 40%, believed that the food or pharmaceutical ingredient sector is the most active/proactive force behind the nutraceutical concept.

A slightly lesser number said the food manufacturing industry is the most proactive. These respondents suggested that the food manufacturers are providing the "pull," leadership and incentive for ingredient suppliers to develop and market a nutraceutical category, and that tends not be a "push" approach from the ingredient side.

According to respondents in this survey the identification and extraction of biologically available ingredients from either animal or vegetable sources appear to be the keys to the development of the nutraceutical concept in Canada. They also say that the food ingredient sector is leading in this area, and that the food manufacturing industry plays an integral role, in-part because manufacturers have the ability to formulate palatable foods while protecting the bioavailability of nutraceutical ingredients. Two respondents credited advancements in biotechnology for isolating and extracting key ingredients.

4. Has your company or member companies of your industry joined forces with other companies to strengthen nutraceutical activity?

Table 2. Number and type of companies or organizations saying they have formed alliances to strengthen nutraceutical activity

Sector	Yes, have formed alliances	No, have not formed alliances
Ingredient manufacturers, suppliers and distributors	7	2
Food Manufacturers	6	2
Researchers	5	2
Dairy manufacturers	1	1
Pharmaceutical manufacturers	0	3
Herb processors	0	3
Others (wine manufacturer, medical reporter, egg processor, R&D centers, etc.)	0	13

Representatives of 19 (approximately 42%) of the companies stated that they have forged strategic alliances with other companies. These occur within the ingredient sector, the food manufacturing sector, and with academic researchers. Only one of the two dairy firms that participated in the survey had struck a strategic alliance. So it appears that alliances do exist among ingredient specialists, food manufacturers and academic researchers. These companies recognize their relative strengths and weaknesses and partner to either maximize or overcome them.

None of the pharmaceutical company representatives in the survey mentioned a strategic alliance. Some of those who gave a negative answer qualified it with statements like, "not yet," indicating that they would be willing and, perhaps, ready to strike an alliance, if the correct situation and partner were presented.

5. If yes, how would you classify the individual companies in this arrangement? How would you classify the partnership?

Of the 19 companies whose representatives indicated they were currently in a strategic partnership, 10 could not define or classify the arrangement in particular words. The most that could be offered was that their partnerships consisted of a "loosely structured, young team of particular strengths" or "loose, not a very sophisticated environment" or "loosely defined."

The representatives of eight of the companies involved in a partnership said that an ingredient supplier was part of the arrangement. Four indicated that independent nutrition research was a component of their partnership, most likely, as one respondent put it, "to get the facts."

There appears to be no method of categorizing the strategic partnerships in the nutraceuticals area that are currently operating in Canada. The most common denominators seem to be a key ingredient supplier and an independent nutrition research component. According to this survey most alliances are at an exploratory stage.

6. What is the ideal partnership, if any at all, to foster nutraceutical activity? Why?

Forty-two responses were obtained to this question (only three participants had no opinion on what constitutes an ideal strategic partnership). While it is not possible to classify the myriad of responses, the following common features were observed, in descending order of frequency:

More than half , or 23 of the ideal partnerships identified by respondents included a food manufacturer or made reference to a strong food industry role. This, it was stated by one, is a necessity because only the food industry can make these products. While any of the partners in an arrangement can lead, the food science supporting the product must be of high quality.

Eighteen, about 43%, of the respondents included an independent academic research as a vital partner for pursuits in the nutraceuticals area. This research, it was stated, is needed to provide evidence based on rigorous research and unbiased clinical data.

Thirteen, about 30%, of the respondents included the federal government as an ideal strategic partner. The government group would monitor regulatory-compliance and marketing-claims aspects of a project.

Six of the ideal partnerships described made reference to a strong biotechnology component. One individual stated that appropriate technology, specifically biotechnology, is mandatory.

In four of the ideal partnerships, including both a pharmaceutical company and a food company was seen as important. The rigid research methodology and regulatory-compliance skills offered by a pharmaceutical company were thought to balance the speed of response to consumer demand and consumer acceptance of the food company.

Again, any combination of strategic partners is possible. Companies seek out others "with something to bring to the equation." However, the ideal alliances in Canadian nutraceutical partnerships would include: credible, high quality food processors; researchers capable of independent, scientifically sound research; the federal government; leading biotechnology support; and pharmaceutical support. It is interesting to note that pharmaceutical support was

mentioned as part of the ideal, but not as part of the strategic alliances currently in existence and operating.

Product definition and product format

7. Please name the type of nutraceutical food ingredients and/or food products your company currently produces?

Thirty-five companies named more than 65 food ingredients and food products under production that they believe to have nutraceutical value. The products span the entire range of the vegetable kingdom and include selected species from the animal kingdom such as shark, lobster and fish oils.

1. herbs, e.g., chamomile, alfalfa leaves, raspberry leaves (herb processor x 2)
2. ginseng, vitamin supplements, enzyme supplements, herbal products (herb processor)
3. antioxidants, vitamins, polyunsaturated fatty acids (pharmaceutical company)
4. sugar replacements, meal replacements
5. vitamins, dietary fiber (pharmaceutical company)
6. fat burner□burns fat instead of generating lactic acid from using muscles (academic researcher and small food manufacturer)
7. plant pigments, phytochemicals (researcher)
8. omega 3 fatty acids, shark cartilage (may be anti-carcinogen or treatment for arthritis as sharks don't have bones), chitosan (researcher)
9. soluble and insoluble fibers, proteins, flax seed, linola (ingredient supplier)
10. nitrite-free alternatives which alleviate cancer problems
11. nutritional supplement (physician)
12. high mono-unsaturated fatty-acid sunflower oil (food manufacturer)
13. lysozyme□a natural antioxidant□replaces potential carcinogens like sulfur dioxide (egg processor)
14. GLA, phytoestrogens, flavonoids (researcher)
15. antioxidants from plants, by-products from seafood industry, e.g., nitrite alternatives, marine oils (researcher)
16. evening primrose oil, a source of GLA (ingredient supplier)
17. oat bran, beta glucan (ingredient supplier)
18. wine phenolics (wine manufacturer)
19. designer eggs, with omega 3 fatty acids, which decrease blood cholesterol (fresh egg supplier)
20. borage oil (ingredient supplier)
21. oat bran, GLA, spices, plant extracts (agri-food public relations)
22. formulated, fortified liquid foods, herbal tea, botanical products (regulatory affairs specialist)
23. GLA, omega 3,6,9; bioflavonoids, Carotenoids, licopene, endo-carbonols, basically phytochemicals (vitamin manufacturer)
24. vegetable extracts, fruit extracts, (ingredient distributor)
25. better-for-you sweeteners and dietary fiber□we develop the technology and sell it to outside companies (ingredient researcher)
26. dietary fibers, various amylose starches, mono-unsaturated fatty acids (food manufacturer)
27. cruciferous vegetables in tablet form (Canadian Health Food Association)

28. vitamins, botanicals, herbs, fiber, fructo-oligosaccharides (product developer)
29. mustard with antioxidant properties, sage or rosemary extracts as antioxidants (ingredient supplier)
30. oat flour, stabilized wheat germ, wheat bran, oat bran (food manufacturer)
31. biogums (xanthan gum), alginates, sweetener substitutes, fat substitutes (ingredient supplier)
32. infant formulas, infant nutrition products (dairy processor)
33. omega 3 fatty acids, antioxidants, herbal components, amino acids (researcher)
34. low-fat yogurt and live bacterial cultures such as acidofilus and bifidus (dairy processor)
35. proprietary (x 4)
36. none currently (x 6)

At least 65 nutraceutical products were named from among 45 companies that had representatives interviewed in this survey. The range of products with nutraceutical potential, as perceived by the respondents, was very broad. It was also a good representation of the many food ingredients and agricultural products native to Canada. The breadth of the category is an indication that there may be export potential for some, if not many, of these products, should their nutraceutical activity be proven and the food products correctly marketed.

8. Have you been able to establish health benefits for these products? If yes, which ones?

Twenty-six of the 35 companies that named nutraceutical products, representing a broad cross-section of the food industry, answered this question affirmatively. The sector breakdown is as follows:

♦ researchers	7
♦ food manufacturers	6
♦ herb processors	3
♦ pharmaceutical	3
♦ ingredient sector	3
♦ other	4

Respondents (business owners or researchers) believed that the following health benefits have been established for Canadian products:

1. Herbs have health benefits established over many years of use□some go back centuries. But, we need a DIN or a health license to legally say anything.
2. Ginseng is anti-carcinogenic; provides immunities; reduces stress and anxiety; increases energy levels. Echinecea is a natural immunity enhancer, helpful at the onset of a cold or flu.
3. Yes, all of them: antioxidants, vitamins, polyunsaturated fatty acids.
4. Only in Germany where we make bold claims on primrose oil and herbal teas.
5. Only those the government will allow (pharmaceutical company).
6. Absolutely!... there is a specific herb correlation with respect to the relief of colds, constipation, cancer and ingestion of that herb.
7. Yes, the access bar can improve fitness by burning fat.
8. Omega 3s do not decrease cholesterol, they decrease triglycerides which are considered a risk factor by many reputable clinicians.
9. Yes.

10. All the potential ones—we're at the beginning.
11. Nitrite is linked to carcinogens, thus this seal-pigment replacement could alleviate stomach cancer.
12. Yes, this enteral product resolves gastrointestinal diseases, inflammatory bowel syndrome, as well as asthma, eczema and migraine headaches.
13. High-oleic canola oil sold in Canada could decrease cholesterol leading to a decrease in the risk of CHD.
14. Only those which have been properly evaluated, e.g., phytoestrogens from flax. Others need better work, e.g., GLA, to establish health benefits.
15. GLA for atopic eczema; cyclic mastalgia; diabetic neuropathy (common pathways for all 3 pathologies).
16. Clinical trials and as yet unpublished studies show benefits for both oat bran and beta glucan.
17. Omega-3 eggs were originally developed for pregnant women to alleviate cerebral palsy in children caused by mothers low in omega 3's at time of conception. They have now been shown to decrease blood cholesterol.
18. Yes, and herbals are on the forefront.
19. Yes, sugar beet fiber has been tested on animals in the States and has been shown to reduce blood cholesterol.
20. Dietary fibers, various amylose starches, mono-unsaturated fatty-acids. Links have been found with most of these.
21. All Bran can make claims on constipation in Japan; Psyllium can make claims on cholesterol reduction in Australia. No claims can be made on these products in Canada.
22. Some of the vitamins, e.g., beta-carotene, various fibers.
23. Some, e.g., wheat germ which is a source of vitamin E; oat bran for dietary fiber; oat flour is used in a pharmaceutical product.
24. There are some disease- related benefits from passive immunities obtained from consumption of our infant formula (for infants).
25. Absolutely, almost all! e.g., omega 3s; antioxidants; herbal components; amino acids.
26. Low-fat yogurt increases the body's calcium level. Second, the live bacterial cultures acidofilus and bifidus provide beneficial functions as harmful bacteria in the intestine are fought off.
27. Proprietary. (x 2)

It should be noted that, although respondents felt that the above health / food benefits have been established, in many cases their belief is not supported by scientific data.

Seven respondents said their company would promote a health benefit only if it were supported by objective, clinical data. These companies indicated they have not established health benefits for the following reasons: the cost of clinical research; the lack of a suitable research and testing protocol; or the lack of a patent to provide exclusivity.

Ten companies indicated they have not established health benefits for their products. As one person explained, "They have just started to appear."

9. Are there health benefits derived from these products which you believe are present yet have been unable to establish? If yes, explain.

More than half, or 26 of the 45 companies interviewed answered affirmatively. Their explanations and comments are summarized below in descending order of frequency:

- Yes, we are just now developing the skills and technology to isolate, evaluate and research properly. (researcher x 2) (ingredient supplier x 2) (ingredient supplier x 2) (agri-food public relations) (trade association) (food manufacturer)
- Lack of consensus on the data is preventing some claims from being established. For example, in 200 epidemiological studies a correlation has been drawn between beta-carotene and cancer. For poly-unsaturated fatty acids, we have significant scientific agreement with respect to blood cholesterol levels. The problem is protocol design there are many interacting variables. Individual responses differ due to genetics, lifestyle, and rates of absorption. Further... "we can't have a placebo for 25-year studies to evaluate chronic disease relationships. This could hurt people, yet is necessary for us to make some kind of claim." (pharmaceutical) (egg supplier) (vitamin manufacturer) (product developer) (dairy processor) (ingredient supplier)
- Yes, psyllium, but it did not receive government approval. (researcher) (food manufacturer x 2)
- Definitely, but we lack the sophisticated scientific data to satisfy the government. (pharmaceutical) (ingredient supplier)
- Yes, but we lack the funding to do the research to establish the benefit. (pharmaceutical) (ingredient supplier)
- We know the benefits of the herbs but the research is too expensive and is dominated by the pharmaceutical giants, by the government and by the R&D protocol/structure. (herb processor)
- We believe some are present but need to partner with a downstream company to do that research for us. (ingredient supplier)
- Most definitely, due to lack of funding to do the R&D, because shareholders want short-term results. (food manufacturer)
- Yes, for GLA; we can't look at every system. (ingredient supplier)

The most common reason stated for unestablished, yet believed-to-be present health benefits associated with food products is lack of scientific protocol/structure. This was cited by eight respondents, equaling approximately 30% of the group in this situation or, alternatively, by more than 15% of all 52 respondents.

The next most common reason, stated by six participants, was conflicting data. This may be because there is no standard scientific research protocol being used. It may also illustrate the infancy of the field and the need for further research to achieve consistent results.

Difficulty in getting government regulatory approval was mentioned, followed by the cost of clinical trials.

Seven of the respondents reiterated the barriers to health-benefits claims mentioned in response to Question 8, i.e., the cost of clinical research, the lack of a suitable standard protocol and the lack of a patent to provide exclusivity.

An equal number (seven), "Couldn't say." Two respondents answered, "Not applicable."

Three respondents stated that they can establish all health benefits they believe to be present in their products.

The majority of companies believed that their products have health benefits and indicated that they have established these benefits to their own satisfaction. However, when asked, it was evident that they tend to lack the scientific evidence required to support the health benefits claimed for their product.

Lack of funding for (the cost of) clinical trials was the fourth most commonly mentioned reason for not having established health benefits of nutraceutical products. However, this was preceded by three other reasons, listed in descending order as follow: inadequate scientific protocol, scientific discord, and disapproval on the part of the Health Protection Branch. It may be that the cost of clinical trials is the bottleneck to the resolution of the first three barriers. Clinical trials are required to define acceptable scientific protocol and to achieve scientific consensus.

10. Are these products marketed domestically or internationally? If internationally, which countries and why?

Table 3. Countries in which nutraceuticals are being marketed by various sectors and why.

Sector	Domestic Only	Both	Int'l Only	Country and Reason
Herb Processors		x		Caribbean Islands, Hong Kong, Hungary, Malaysia, U.S.: size of pop'n and market readiness
Pharmaceutical		x		Germany, South Africa, France: can make claims, +140 dev'd countries where chronic diseases occur
Food Manufacturers		x		U.S., Taiwan, Singapore, Australia, N.Z., Cyprus, China: nutrient claims, health claims Europe, Netherlands: market readiness, consumer acceptance Japan, Far East, Asia, Europe: cultural acceptance
Ingredient Suppliers		x		Western Europe, Asia, Pacific Rim, U.S.: readiness of markets Japan, Europe: publish health claims, demand, volume potential
Herb Processors			x	Orient and Europe: cultural acceptance
Ingredient Suppliers			x	In 42 countries: legislated claims, market acceptance
Food Manufacturers			x	12 free-enterprise countries: came seeking our egg technology Japan, Australia: nutraceutical claims permitted Italy, France, Belgium, Denmark, Spain, Orient: ripening agent in cheese
Researchers			x	China: volume, consumer acceptance International markets: economies of scale, patents South Korea, Japan: can make claims

Dairy Processors	x	Western Europe, France, Germany, Balkan countries: regarded as part of culture Jordan, Poland, Ukraine, N.Z., Switzerland, Europe: product exclusivity and acceptance

Of those companies whose representatives stated that they are marketing nutraceuticals, none indicated that they are doing so in Canada only. Seventeen indicated they are marketing internationally only, primarily because of the following factors:

- the ability to make health claims because of legislation or long-standing consumer acceptance based on cultural traditions and folklore, and
- size of market and volume potential

Sixteen companies indicated they operate both in Canada and abroad. However, the foreign markets appear more lucrative for the reasons listed above.

Consumer acceptance resulting from tradition and because of supportive government legislation seem to be the determining factors in the selection of a market in which to sell nutraceuticals. The factors determine market size and volume potential.

11. Can you name the types of food ingredients and/or food products your company and other Canadian companies currently produce that have nutraceutical potential?

At least 10 respondents answered with, "Proprietary," "The same as current," "Can't say" or "Not applicable."

Sixteen respondents named approximately 40 potential nutraceuticals they are currently researching or intend to research in the future. The following is a list of potential nutraceuticals, in the minds of respondents:

1. golden seal; gingko; other Chinese herbs; vitamins and minerals; calcium (herb processor)
2. Carotenoids; phytochemicals; fat replacers (pharmaceutical)
3. primrose oil (pharmaceutical)
4. fish protein concentrate (researcher has the technology but lacks the raw material)
5. antioxidants, omega-3 fat-based products (researcher x 2)
6. folic acid in orange juice; beta-carotene in vegetable juices; dietary fiber in apples (food manufacturer)
7. a blended oil to affect blood lipids; a fiber product to decrease glucose and cholesterol (medical physician)
8. extracting milk proteins which in vivo work against pathogens; other antimicrobials (food manufacturer)
9. combine GLA with other compounds, e.g., primrose oil + marine oils, which is a best seller in Europe (ingredient supplier)
10. an E. coli antibody which can be extracted from the egg after chicken is fed special feed (egg processor)
11. garlic we plan to eliminate the flavor and odor and market it for its medicinal compounds (ingredient supplier)
12. more herbs and botanicals (regulatory affairs consultant)

13. omega-3 fatty acids and, perhaps, an antioxidant, but research isn't as strong for the antioxidant (food manufacturer)
14. cruciferous vegetables, soybean, flax, multivitamins, dietary supplements (trade association)
15. alpha-lactobumin; lactoferrin; immunoglobulin; calcium; potassium (dairy processor)
16. more cultured dairy products (dairy processor)

An additional 10 respondents were not product-specific in their answers, yet indicated that many opportunities exist to develop potential nutraceuticals. Answers offered were: "All foods are potential candidates" or "All agricultural products have potential" or "Anything that can be produced in Western Canada, but development requires joint venturing" or "Many, and they're all ag biotech-based."

To repeat the observation of one respondent, the potential nutraceuticals are "Limitless, the gamut of the kitchen table." Canadian products with nutraceutical potential tend to be a natural outgrowth of a company's existing expertise and resources, differing little from the other products with which they are involved. Companies from dairy processors to herbalists, cereal chemists to marine oil specialists, tend to build upon their past successes and present strengths, pursuing product extensions of their base businesses. One respondent summed up the rationale for most potential nutraceutical products, in both general and specific terms: "We will pursue fortification of our basic product line with proven key active ingredients."

12. Is the market for these nutraceutical-potential products domestic or international? If international, which countries and why?

Almost all respondents indicated they will continue to market in those areas they cited in response to Question 10. They explained that they enjoy success in these countries, and will build on the expertise they have gained.

The nutraceutically active companies in Canada appear to prefer to offer new products to consumers in markets they already understand, rather than to pursue new markets.

Nutraceutical activity determinants

13. How did your company select which area of nutraceuticals, the prevention or treatment of disease, to pursue?

Representatives of 43 companies answered this question. In total, 36 companies could identify the strategy by which they came to pursue nutraceuticals.

Twenty of these had pursued a market-opportunity-first approach, with the following pattern:

1. Identify a public health issue, consumer need or market opportunity.
2. Review or be aware of scientific studies which show a link between the ingredients the company works with, and the physiology related to the public health issue.
3. Recognize this as an opportunity to expand the base business and add value to familiar ingredients, processes or technologies.

Sixteen indicated they had pursued a product-value-added-first approach, with the following pattern:

1. Start with an ingredient and product you know.
2. Glean nutritional clinical data, add value to the ingredient by optimizing current technology and design something to provide the appropriate nutraceutical benefit(s).
3. Determine if the value-added ingredient is deliverable in a food system that provides that physiological function.
4. Scan a different set of clinical information on consumer needs and market opportunity.

The first approach is market opportunity-driven. Companies are scanning literature, listening to consumers and health professionals. They recognize an opportunity to add value to their business by targeting a public health issue or fulfilling a consumer need. The second approach is value added-driven. Companies research their products, then seek market segments that will benefit from the attributes of these new products. Both approaches could be used by one company over time.

The remaining seven company representatives who answered this question were unable to outline a clear strategy. Some openly admitted to fortuitous, serendipitous accidents (e.g., aspartame). However, as one researcher said, "I can't plan my research hoping for an accident." One dairy processor had simply identified and promoted latent benefits thousands of years old.

Perceived consumer awareness / readiness

14. Do you believe that Canadian consumers are aware that foods and food ingredients can play an active role in the prevention and treatment of disease? Do you have any data to confirm your answer?

Twenty-eight, or approximately 60% of the respondents answered with an unequivocal affirmative, such as "Yes," "Definitely," "Oh, sure" or, "The majority do." This answer was evenly distributed across the food industry sectors represented in the survey. These respondents quoted data to support their view, something respondents with countering opinions were not able to.

With respect to data to confirm their positive answer, responses and frequency were as follow:

♦ observing product sales, i.e., yogurt, oat bran, herbs, vitamins	8
♦ National Institute of Nutrition studies [surveys]	7
♦ industry-sponsored focus groups	4
♦ no data	4
♦ GMPC studies	2
♦ newspapers, consumer magazine articles	2
♦ Heart Smart Surveys/Program	2
♦ other	2
♦ no Canadian data available, only American data	1

(The total was 32 because of some multiple answers)

Nine respondents felt that Canadians' awareness of an active role played by food ingredients in the prevention and treatment of disease is growing or improving. Most of this opinion was from those working in the ingredient sector of the food industry. Only three could confirm their

answer with data: Institute of Food Technology 1994; the growing consumer practice of reading labels and seeking out active ingredients; the growth in sales at health food stores.

Eight respondents, representing all food sectors surveyed, felt that Canadians had no knowledge or very limited knowledge of nutraceutical potential in food. Few could quote data to support their answer. Supporting comments received included:

- "I know this due to my exposure to consumers and my retail front experience."
- "This knowledge rests with the food companies."

The majority of the respondents (28, or 60%) believed that Canadian consumers are aware of or becoming increasingly aware of the nutraceutical potential in food. Moreover, only this group of respondents could confirm their answer, by quoting published Canadian surveys such as NIN and GPMC, sales growth of pertinent products, the results of industry focus group discussions, etc.

This positive belief, substantiated by objective data in some cases, may explain why the majority of the Canadian companies surveyed are optimistic about the opportunities presented by the nutraceutical concept.

15. If yes, can you briefly describe the type of promotion activity your company will or can put in place to promote your nutraceutical product(s) to Canadian consumers?

Thirty-five respondents answered this question. Those not responding considered it to be out of their area of expertise or had not thought about it.

One respondent summed the situation up for all "...this is a tough game to market."

A few respondents stated that, "Very little can be done to promote nutraceutical products to Canadian consumers," adding that, "Nothing can be done about disease," as the *Food and Drugs Act and Regulations* prevent promotional messages of this nature. Thus, any promotion is subtle and small in scale.

Thirteen respondents, half from the food manufacturing industry, indicated that they make indirect claims by involving the health-care community in their promotion campaigns. They share technical results with physicians, publish results in the medical media, hold medical conferences, attend conventions such as the Canadian Dietetic Association Conference and sponsor events at wellness centers. The health-care professionals share the message with consumers, making either direct or indirect links between the product and a health benefit.

An equal number, or 13, mostly from the ingredient and academic research sectors, would publish clinical results, indirectly suggesting medical benefits of nutraceutical products through the consumer and trade media. No mention was made of contact with health-care professions or health-care professional literature.

A few stand-alone answers were received, such as:

- Undertake consumer-needs research to work at alleviating consumers' confusion. Then, promote only established medical benefits through Temporary Marketing Permits (TMPs) supplied by the Health Protection Branch.

- Promote in other countries first, such as the U.S. and Europe. When [it] flows back, Canadians will support the product. (x 2)

The first comment describes a practice that a number of respondents said they use. One firmly believed that all indirect promotional activity, no matter how sound, is done because of health claims are not permitted.

The last comment, heard twice here and in other parts of the survey as well, illustrates the global society we live in, the power of information transfer from one country to another.

Dissemination of information through indirect promotional campaigns, which may or may not involve medical or health-care media, seems to be a primary method of promoting the benefits of nutraceuticals to Canadians. The technical data supporting the implied benefits of a product must accompany the message. While this indirect method is regarded as inefficient and expensive, it is employed because of the belief, as illustrated in Question 14, that Canadians will associate particular foods with health benefits, and because *the Food and Drugs Act and Regulations* prohibit direct claims.

16. If no, what is required to bring about the required level of Canadian consumer awareness?

Twelve respondents believed that Canadian consumer awareness of the health benefits of particular foods is low. Two remedial suggestions were received:

- Change the regulatory framework to allow one to speak freely on the benefits of nutraceuticals. (x 3)
- Educate practically every Canadian on the nutritional importance and nutraceutical value of food.

Raising consumer awareness of the health benefits of particular foods could involve a multisectoral promotion strategy that includes public health professionals, all educational institutions, all levels of government, and the medical community. The effort would require a supportive regulatory framework and consensus among nutritionists and researchers with respect to health claims on food.

17. Will and how would your promotion activity then change?

The 10 or so responses to this question can be summed up in one: "Our promotion activity would not change, but our activity level would. Our work would not be falling on deaf ears."

It is thus likely that companies would continue to include the health-care professionals and the media in their promotional work, once Canadian awareness of the potential of nutraceutical products had risen to an adequate level. However, with the synergy provided by an educational campaign on nutraceuticals, and with the support of legislation, companies would be motivated to launch more products and undertake more promotional activity.

18. Which channel(s) of distribution is(are) most appropriate for delivering nutraceuticals to Canadians and why?

The following three types of retail outlet were suggested: grocery stores, health food stores, and pharmacies. Thirty-two, or more than 65% of those responses indicated grocery stores as the most appropriate distribution channel for nutraceuticals in Canada. This view was held by representatives in all the food industry sectors in the survey. Reasons given to support this opinion were as follow:

- Grocery stores are the most accessible channel. (x 5)
- Nutraceuticals should be sold as standard foods accessible in grocery stores. This would alleviate the possibility of overdosing, a risk with tablets. (x 4)
- Grocery stores offer the correct price for consumers. (x 4)
- Grocery stores can handle more volume. (x 2)
- Grocery stores are a traditional outlet. Purchase here will overcome consumer inertia. (x 2)
- Grocery stores are required to discover the benefits of the foods we already eat.
- The pharmacy section of the supermarket, as we're looking at only 40% of Canadians who will supplement their diets. (x 2)
- For "soft" products, e.g., prevention of disease, go to the grocery store.....for "hard" products, e.g., of therapeutic value, go pharmacy (Over the Counter or prescription, depending on the intensity of the active ingredient).
- To reach the masses and popularize the notion of eating well without going back to brown rice. This avenue [sales through grocery stores] is required to meet objective of decreasing health care costs.

One respondent preferred pharmacies, reasoning that consumers frequent these establishments because they are looking for help. The pharmacist is seen as part of the health-care team and physicians may not know the side effects.

A number of respondents spoke out against pharmacies for distribution of nutraceuticals, quoting the following reasons:

- Pharmacies have [too high] a cost structure.
- Pharmacies are the wrong way; it tells people this is a drug.
- It is not right to have Kellogg's bran buds medically prescribed at the drug store.
- Drug stores are not frequented every day. If [this] was for the elite, drug stores would be appropriate. (x 2)
- Consumers looking for these products are looking for information. Pharmacies are going self-serve as their labor costs are too high.

Five respondents preferred health food stores as the appropriate distribution channel for nutraceuticals. Reasons to support their answers included:

- The health food store clientele has more awareness than the general public.
- Health food stores are accustomed to handling niche market products and are familiar with regulatory bodies.

- The proprietor of a good health food store will want scientific data noting observations, side effects, and benefits. They want to help their customers and loyal users.
- Health food stores are more science-oriented.
- This is where the public expects to find these products.

Three participants did not see any particular distribution channel as appropriate. They suggested that sheer market force will determine if nutraceuticals are sold at health food stores or at warehouse clubs.

Two participants had novel suggestions. One was in favor of distribution at a health-care facility, only so as to portray professional endorsement. Another felt that marketing through networking is required to educate the customer about the products' benefits.

A large majority of the respondents envisioned grocery stores as the most appropriate distribution channel for nutraceuticals, citing accessibility, mass-market pricing, conveyance of the product as a food and for consumer trialability. Many of these respondents not only spoke in support of grocery stores, but reasoned this choice over other avenues, such as health food stores and pharmacies. Some respondents were not in favor of the pricing structure of drug stores and the implied image of a nutraceutical as a drug.

19. Do you believe that international consumers are aware that foods and food ingredients can play an active role in the prevention and treatment of disease? In which countries?

All 45 respondents answered this question affirmatively. Some gave an unequivocal "Yes" and "Absolutely." Others simply alluded to a steadily growing awareness. Many freely added that, "International consumers' awareness is much higher than that of both Americans and Canadians."

As to which countries, multiple responses were received from most participants. The most commonly cited countries by far, in descending order, were as follow: Japan, Pacific Rim countries, Asian countries, the U.S., European countries, Germany and the Scandinavian countries.

Some generally referred to sophisticated and developed markets operating in those countries as the areas where awareness is high.

20. If yes, can you briefly describe the type of promotion activity your company will or can put in place to promote your nutraceutical product(s) to these International consumers?

Thirty-six respondents answered this question. Twenty-three of these, about 65%, stated that promotional activity to "these" international consumers would involve direct health claims, either general or specific. One respondent cautioned that all of these claims are "functional claims"—they are not specific health claims. In some countries (e.g., Japan), product claims must be supported by peer-reviewed scientific data; in some countries (e.g., China), thousand-year old anecdotal information is sufficient; in some countries (e.g., Switzerland), claims have been grandfathered into legislation as a result of centuries of use of the product and its cultural associations.

A smaller number of respondents (six), indicated that they would conduct promotional activity in foreign markets only with a host marketer or after having accounted for and assimilated cultural differences. Suggested means by which these cultural differences can be accommodated were as follows:

- Making good products available is a good start; food which is palatable and appeals to the host country.
- Knowledge of international marketing is essential, knowing how different cultures have differing nutraceutical needs.
- Align with a company in that country which provides scientific data and examples that the product is effective.

Claims are permitted in some countries but there varying requirements for substantiating them. The Canadian respondents seemed to know of the requirements for particular markets and whether they already have, or could acquire the necessary data to export products there. Overlooking cultural practices by simply providing supporting data for health-related claims will not ensure market success. It is necessary to position the active ingredient in food which is conducive with the eating patterns in host countries.

21. If no, what is required to bring about the required level of consumer awareness to these International consumers?

22. Will and how would your promotion activity then change?

Questions 21 and 22 were not applicable because affirmative answers were received for Question 19.

Market selection

23. Is most of your market focus domestic or global/international?

Forty-three companies answered this question. Three, all in the ingredient sector, said they devote equal focus to both types of market. Of the remaining 40, half said they have more of a global/international focus and half more of a domestic focus. The branches of multinational food and pharmaceutical companies tended to have a strong domestic focus. The ingredient sector, small specialized companies in the food manufacturing sector, and the academic research sector seemed to have a predominantly international market focus; they quoted supportive host-country legislation as the reason.

24. For the latter, which countries are you targeting and why?

In almost all cases, the targeted countries are the same as those mentioned in Question 19: Japan, Pacific Rim countries, Asian countries, the U.S., European countries, Germany, and the Scandinavian countries. The reasons given were: legislation that permits claims, developed countries with higher consumer awareness, volume potential, and familiarity with the cultural and required marketing strategies. The U.S. was considered a target market because of its accessibility and proximity.

Relatively small companies with nutraceutical products, either ingredient suppliers or food manufacturers, stated that they will seek out international markets in which they can prosper. They considered market-potential determinants to include supportive legislation, consumer awareness, volume potential, and past specific experience. Companies with a major domestic focus tended to be branch plants of multinational food or pharmaceutical companies.

Strengths, weaknesses, opportunities, threats (SWOT)

25. What forces will grow a Canadian nutraceutical industry? Identify as many as you wish, ranking in order of importance if possible.

More than 150 separate mentions were made. Those most frequently given, in descending order, are as follows:

- consumer demand and consumer awareness due to: an aging population; a desire to decrease one's own health care costs; a desire to live longer and healthier; mistrust of traditional medicine
- a federal regulatory climate which permits health claims
- industry responsive to the consumer demand for nutraceutical products
- the necessity to reduce health-care costs at all levels of government
- technology and science: technology to isolate the ingredients and protect their bioavailability; excellent science to formulate the right food products and substantiate justifiable claims

Consumers and their demand for quality of life are fueling the nutraceutical "revolution." Industry and research are attempting to meet this demand. Advanced technology and improvements in science may bring about a regulatory climate that allows for the health claims consumers are becoming more aware of and seem to be demanding more of.

26. For each of these, or as many as you can, please comment on your company's or your industry's ability to capitalize on these domestic opportunities.

Five of the 45 respondents answered that such is not possible, citing legislation as the major impediment to industry initiatives. One respondent cited lack of adequate technology to meet their requirements, another cited lack of adequate consumer awareness.

All other respondents answered that their company/industry can capitalize on growing consumer demand for nutraceuticals—some clearly, some with some qualifications. The most commonly cited requirements to realize domestic opportunities were as follow:

- Develop a strategic partnership with at least one other company.
- Market in specific niches and be entrepreneurial.
- Formulate, launch, claim, and deliver improved health.
- Target the $1.8 billion spent on health-care; change those expenditures over to food expenditures.
- Adopt a clear marketing strategy with the right product.
- Drop the "pharmaceutical" mentality.

The requirements to groom a domestic nutraceutical market are similar to the basic strategic steps to adopt new business ventures. Strategic alliances, niche marketing and a clear marketing strategy are the priority steps.

27. What forces will grow an international nutraceutical industry? Identify as many as you wish, ranking in order of importance if possible?

A substantial number of the respondents, about 25%, referred to their response to Question 25, meaning the forces operating in the Canadian domestic market are identical to those operating in an international market.

The most commonly cited forces to groom a specific international nutraceutical industry, in descending order, were:

- Nutraceutical success in one country will grow nutraceutical success in others.
- Harmonization of regulatory procedures and permissible claims in all countries, e.g., CODEX has proposals covering some of these aspects; the WHO and FAO are looking at simple ways of making people healthy.
- An increase in the number of developed countries in which people have a higher income.

Some respondents interpreted this question to mean, "What forces will grow a viable nutraceutical export business for Canadian companies?":

- Canada has a lucrative opportunity to conduct competitively priced research [at a reasonable cost]. There are excellent facilities at universities; the government has technology to share; the country has a low dollar. Other countries are simply seeking out the sources of nutraceutical products and Canada is one of them.

- Canada has Good Manufacturing Practices (GMP). Canada grows a high quality ginseng. The name Canada is synonymous with quality. We can produce quality and meet demand. We need more awareness of the international market requirements and what we can do.

Consumer demand, research, a supportive regulatory climate, international development, global travel, and increasing consumer health consciousness leading to exploration of alternative medicines and an inclination toward self-medication, will foster an international nutraceutical market. However, this can be either enhanced or hampered by lack of regulatory harmonization among countries. Current exporters of nutraceutical products indicate that there is a foreign market open and receptive to the goods and services Canadians have to offer.

28. For each of these, or as many as you can, please comment on your company's or your industry's ability to capitalize on these international opportunities.

Thirty-four responses were received, all in the affirmative. Almost all respondents referred to the same requirements they gave in response to Question 26:

- Form a strategic partnership with at least one other company.
- Niche market through brazen entrepreneurship.
- Formulate, launch, claim, and deliver improved health.
- Target health-care costs; change those expenditures over to food expenditures.

- Adopt a clear marketing strategy with the right product.
- Drop the "pharmaceutical" mentality.

The survey results indicate that to succeed in a nutraceutical export business, the other partners must be the Canadian federal government and a host country entrepreneur. The strategic steps required to groom an international nutraceutical market were deemed to be the same as those normally required to adopt any new business venture. However, to export it seems that it is considered important to have the assistance of the Department of Foreign Affairs and International Trade and a host country sponsor.

29. Do you believe there are domestic market barriers to entry which prevent the evolution of a Canadian nutraceutical industry? If yes, what are they?

More than 125 mentions were made. Thirty-eight respondents, almost 85%, mentioned *the Food and drugs Act and Regulations* as a barrier, most as the primary barrier. This barrier was stated to have the following effects:

- A manufacturer cannot communicate a nutraceutical benefit, functional claim or health claim on a food.
- It is slower here than elsewhere, making it more expensive and difficult for entrepreneurs.
- Good nutraceutical foods are not on the Canadian market because they haven't gone through the regulations, which is different and difficult in Canada.
- Frustrating—we miss opportunities by not bothering.

Respondents expressed a great degree of frustration with the government regulatory system and emphasized the need for it to change quickly in order to become more responsive to the nutraceutical industry and market. Others felt there should be more instruction and guidance given by government, especially with regard to what standards and procedures must be followed to get products approved.

Other barriers mentioned, in descending order of frequency were as follow:

- lack of consumer awareness; need for consumer education
- marketing, production and research costs
- lack of teamwork among and between academia, industry and government agencies
- lack of awareness and need for education on the part of the medical profession, other health-care professionals, government and industry
- varying levels of consumer literacy

The *Food and Drugs Act and Regulations*, which prevents health claims on foods, or advertising food as treatment for any of the diseases in Schedule A, is seen as the major barrier to the nutraceutical market. What was seen as lacking is an approval process for developing the nutraceutical potential of Canadian foods.

The remaining barriers were related to marketing, product and research costs, and a lack of awareness among the public, industry and the medical profession.

30. Is it possible to maneuver around these barriers? Can you provide an example?

Thirty-seven, or almost 82%, answered in the affirmative. A few carried the attitude, "Certainly, everything is possible." However, most added that maneuvering is inefficient and costly. Many regret this practice as it could have a negative effect on trust and credibility.

There were two types of maneuvers cited: indirect promotion through the medical community and working directly with Health Protection Branch authorities:

- developing a "consumer link" via indirect promotional literature through indirect communication vehicles
- marketing by innuendo. Juxtapose a public study against an ingredient list and let the consumer make the connection.
- Advertise on U.S. television. Send out scientific data to the consumer medical media.
- chiropractor selling as an endorsement
- Conduct excellent research and work with the authorities.
- Some industry groups bring the regulatory people to their research and development site; one mentioned Saskatchewan, where Feverfew (a herb) is being investigated as a treatment for migraine headaches—limited claims about this benefit of the product are permissible.

There was a great degree of optimism among the respondents, seemingly saying, "If there's a will, there's a way." If necessary, they will maneuver around the regulatory barrier. However, it is costly, inefficient and can be prone to unsubstantiated health claims. Some examples do not appear credible, however legal they may be. Some practitioners prefer to work directly with the authorities, involving them in the task of validating a nutraceutical claim.

31. Are any of these domestic market barriers impossible to address? Can you elaborate?

Twenty-eight, or almost 62% of the respondents answered, "No," supported by comments such as:

- We want to break through them; nothing is impossible to address.
- The regulatory framework is starting to soften already. The government is motivated by the need to decrease health care costs.
- Somewhere there is a solution for everything.
- Nothing is impossible—just counter-productive.

Of those who feel there are domestic barriers impossible to address, the most commonly mentioned is the regulations on health claims. Other impenetrable barriers suggested were financing and an inability to identify the appropriate market segments.

Most respondents believed the current barriers can be addressed. However, they would prefer to operate in a direct rather than circuitous fashion, which occurs while maneuvering around barriers. The respondents who believe there are domestic barriers impossible to address commonly mentioned the *Food and drugs Act and Regulations*, labeling them as impossible or too costly with which to comply. Not to be overlooked is the need to educate Canadians on the nutraceutical benefits of some foods using communications vehicles and techniques that accommodate a cross-section of educational levels.

32. Do you believe there are market barriers which prevent Canadian companies from accessing an international nutraceutical industry? If yes, what are they?

There was an almost even split among the respondents, from every sector represented, between an affirmative and a negative answer. For the most part, it was perceived that there are fewer barriers to an international nutraceutical market than the domestic one.

The most commonly cited international barriers, in descending order of frequency, were as follow:

- the regulatory system operating in each country
- lack of harmonization of regulations among countries
- tariff and trade barriers
- patent issues

A few respondents commented on the Canadian opportunities in the international arena. Encouraging comments put forth included the following:

- Canadians have only themselves to fear.
- The image of Canadian products is very good. If we can meet [host market] labeling requirements, we shouldn't meet any objection.
- Canada has an excellent image from pharmaceuticals and from agriculture.
- In Canada, we make smaller runs and tackle a very specific market. International manufacturers won't make small runs just for Canada. Therefore, we can make small runs and satisfy domestic as well as foreign niche markets.
- The federal government wants HACCP, GMP, ...ISO 9000 is coming. All this will apply to nutraceuticals. This is good for Canada, e.g., our Department of Fisheries & Oceans standards are used internationally. This helps us get into an international market because we set the standard.

Almost half the respondents believed there to be no international barriers to nutraceutical market development, while the other half named at least one. Those with export experience are encouraged about opportunities for Canadian nutraceutical companies in export markets and cite the quality of Canadian standards and products as a strength to be built upon.

33. Is it possible to maneuver around these barriers to an international market? Can you provide an example?

Only those with export experience answered this question with confidence. The most common answer was, "Yes," and the most common approaches mentioned were as follow:

- working with the host country's regulations; build a base locally, prove value
- Learn where the tariff hits—if value is added in our country, it eliminates these barriers.
- Do a cost/benefit analysis before accessing a larger foreign market.
- Use scientific research, user feedback and good products; then efficacy cannot be denied.
- Understand the cultural market in that country, from taste buds up. Formulate for that country.
- Maneuver through EDI. Get the information you need to get what you want.

Those with export experience have learned to maneuver strategically and tactically. They have also learned to be sensitive and responsive to a host country's legislation, culture and eating patterns. Information and flexibility appear to be the keys to success.

34. Are any of these international market barriers impossible to address? Can you elaborate?

All 18 responses to this question were, "No." It was added, however, that the process is difficult and lengthy. In addition, foreign offices are regarded as very helpful to get [our products into those countries]. To this point, one respondent suggested government involvement to ease and shorten the export/approval process.

International markets appear to be more accessible and foreign host government agencies more cooperative when developing a nutraceutical market than is true domestically. The accessibility of the foreign markets compensates for the cost of conducting business abroad. Government assistance in decreasing the length of the process has been suggested.

Perceived / suggested government interaction

36. Is government involvement appropriate in growing the nutraceutical industry in Canada for a domestic market?

Forty of the 45 respondents, almost 90%, delivered a firm, "Yes" in response to this question. Supporting statements included, "Absolutely essential ...without government, you're in breach," "Yes, if done correctly," "A necessity."

Of the remaining five respondents, two said no, one stating that, "....it hasn't been appropriate for us." Three believed the government should play an indirect, peripheral role in the growth of a domestic nutraceutical market.

There is thus a strong perceived need for government to work with industry in growing a domestic market for nutraceuticals.

37. Is government involvement appropriate in growing the nutraceutical industry in Canada for an international market?

Forty-one of the 45 respondents, almost 90%, delivered a firm, "Yes" to this question, adding comments such as, "A necessity" and, "Necessary and appropriate."

Of the remaining four, three suggested indirect or peripheral involvement. The same respondent as in Question 36 stated, "No," adding that, "It hasn't been for us."

There is thus a strong perceived need for government to work with industry in growing an international market for nutraceuticals.

38. If yes, can you describe the types of activities which the federal government has undertaken which have been beneficial, both domestically and internationally?

Twenty-one respondents, almost 45% of those surveyed, did not describe any activities the federal government has undertaken that have been beneficial, either domestically or internationally. Perhaps this is because some of these respondents are affiliated with

multinational corporations that do not require the foreign assistance or capital support needed by small companies.

The remainder, approximately half of those surveyed, named the following as beneficial federal government initiatives in developing a nutraceutical market, domestically or internationally (in descending order of frequency):

- research grants such as NSERC, IRAP, CFAR and NRC programs; the IRAP network and investment tax credits for research have been beneficial
- international trade activities such as foreign missions, establishing contacts arranged and hosted by the Canadian Embassy in the host country
- Re-engineering of Health Canada is setting the stage for more responsive regulations—the total regulatory review will lead to a more competitive market place and encourage investment.
- indications of loosening of the regulations such as approval of Feverfew for treating migraine headaches; approval of fat substitutes and sugar substitutes
- "Fast track evaluation," which is new this year from the Treasury Board.
- CODEX , where Canada is a leader, will foster international opportunities.

Those who did recount beneficial activities, typically small entrepreneurs and research institutions, seemed to be able to do so because of experience they had acquired in working with government agencies. The most commonly mentioned federal government activities included technological assistance, funding of research, loosening of the regulations and faster approval procedures. With respect to fostering an international market for Canadian nutraceutical products, it appears to be almost essential that the federal government maintain a vibrant and credible Department of Foreign Affairs and International Trade.

39. If yes, can you describe the types of activities which the federal government should embark on to ensure the viability of the nutraceutical industry, both domestically and internationally?

More than 125 suggestions were offered. In order of descending frequency, they are as follow:

Thirty of the 45 respondents, approximately 65%, made an appeal for regulatory reform, i.e., the *Food and Drugs Act and Regulations*. Some suggested a third category for nutraceuticals, separate from the categories of food and drugs, which would permit health claims on food and position food as a therapeutic agent. It was suggested that there be a Nutraceutical Identification Number (NIN) or that a Canadian equivalent of the U.S. DSHEA (Dietary Supplement and Health Education Act) be established. The respondents seemed to favor a regulatory body that would allow health claims on food and, at the same time, evaluate and monitor the scientific and clinical data upon which the claims are made.

Along with this came a request for procedural guidelines for industry on what is required to comply with the legislation. The feeling was that such guidelines could be made available, but have not been. A number of respondents also felt there is a need for education of government agencies so they will recognize nutraceuticals and their porential benefits for Canadians.

Numerous calls were made for a communication strategy that the benefits of nutraceutical products to Canadian consumers, physicians and industry, and raises awareness among all.

A few specifically suggested that the federal government could play a strategic role in reducing health-care costs through the recognition of the preventive [risk-management] effects of nutraceuticals and regulatory reform on health claims.

A very strong appeal was heard for regulatory reform that recognizes the role of nutraceuticals in improving the health of Canadians, and for clear guidelines by which industry can abide. In addition, it was felt that the government could adopt a communication strategy on nutrition and play a significant role via nutraceutical validation and promotion, in decreasing health care costs.

Nomenclature

40. Are there other words you know of which describe foods or food ingredients "that have health or medical benefits, including the prevention and treatment of disease"?

Thirty-three of the 45 respondents, approximately 70%, answered, "Yes" to this question.

41. If so, can you name them?

The most commonly mentioned synonyms for nutraceuticals, in descending order, were as follow:

- functional foods 18
- designer foods 12
- medical/medicinal foods 10
- pharmafoods 5
- phytochemicals 5

Sole mentions included nutri-foods, probiotics, FOSHUs, engineered foods, pharma-nutrients, traditional herbal medicines and clinical foods.

The most common word used interchangeably with nutraceuticals was functional foods, followed by designer foods and medical/medicinal foods. That the majority of the participants knew that there is more than one word to describe "a food which has health benefits, including the prevention and treatment of disease," indicates an awareness of research and development in this area. As one respondent put it "...there's an incredible list."

42. In naming these other words, do they describe the preventive nature or the treatment nature of the food in question, or both?

One researcher differentiated between, "prevention and treatment of disease" and "management of risk factors." The point was that nutritionists can only manage risk factors; they cannot, through nutraceuticals, prevent or treat disease. This thought was also conveyed by a representative of one of the pharmaceutical companies, who explained that, currently, we know very little about the cause and progression of many diseases.

This implies that the definition of a nutraceutical may need to be revised before the products can be regulated. Positioning a nutraceutical as a means of modulating risk is perhaps a more

realistic approach than positioning it as a substance that prevents or treats disease. This distinction may be a key to more lenient regulation. Should management of risk factors (for example, reduction of blood-lipid levels to reduce the risk of coronary heart disease) be the most realistic expectation for these products, then perhaps both the industry and regulators should consider modifying the standard definition of a nutraceutical to reflect this.

Other respondents, in particular the last in the following list, gave answers that tend to reflect the same view, as follows:

- both (x 15)
- preventive nature (x 12)
- treatment nature (x 6)
- Nutraceutical is not the right word—functional food has more meaning; clearly describes the whole thing. (x 1)
- We are walking on a thin line when we speak of treatment; the focus must be on prevention. (x 1)
- Can't say. (x 8)

43. Having discussed what some of these known words describe most about the food, in your point of view, where is Canadian nutraceutical activity focused on... 44. Prevention of disease?... 45. Treatment of disease?

Twenty-six of the 45 respondents, approximately 60%, believed Canadian nutraceutical activity is focused on prevention of disease. Five respondents placed the focus on treatment of disease and 14 did not say or had no idea. Comments offered in support of statements included:

- Few nutraceuticals are used for treatment.
- We need to focus on prevention, both for those who are developing the disease (e.g., CHD) and for those who worry.
- Pharmaceuticals are for treatment; nutraceutical foods are for prevention.
- Neither; the focus is on risk-factor management.

A consistent pattern has emerged. Most of the respondents believed the name nutraceutical implies the prevention of disease. Similarly, most nutraceutical activity in Canada is focused on the prevention of disease. It appears that Canadian researchers and manufacturers are not attempting to treat disease. This is another reason to clarify the role of nutraceuticals. One suggestion would be to remove "treatment of disease," when defining nutraceuticals in Canada.

46. 47. 48. In your opinion, in which of the following sectors is most nutraceutical activity occurring in Canada...food ingredient, food processing, or pharmaceutical?

Eighteen, 40%, of the 45 respondents to this question believed the food ingredient sector to be most active in developing nutraceuticals. The remaining responses and their frequency were as follow:

food processing	6
pharmaceutical	4
even split between pharmaceutical and food ingredients	3

- equal split among all three sectors 3
- biotechnology industry 2
- Can't say. 9

Comments in support of responses were as follow:

- We need the [food ingredient and biochemical] science first, developing the food system after is the easy step. (pharmaceutical company)
- The food ingredient sector makes it possible. Food processing is looking for new ingredients. It is difficult to get pharmaceutical companies to look at it as nutraceuticals are for the food industry.
- The functions are not as separable as it appears as successful [companies] have all three represented.
- Claims are required to get the pharmaceutical sector involved.

Most of the respondents believed the food ingredient sector to be most active in developing nutraceuticals. The greatest disparity among the responses is in regard to the involvement of the pharmaceutical industry. Some participants said all are secretly working on nutraceuticals. Others said they have no expertise or inclination.

In reality, either a food processor or pharmaceutical company can formulate using a food ingredient. However, the active ingredient and its clinical value must first be determined, indicating an important first role by the food-ingredient sector. As shown by the comments offered, there could be naivete on the part of pharmaceutical companies as to the complexity of maintaining the bioavailability of an active ingredient within a palatable food system. Moreover, as alluded to at the outset of this report, a branch of a multinational pharmaceutical company could cannibalize the parent company's active ingredient by marketing a less profitable nutraceutical.

Perhaps the most insightful comment was one stemming from direct experience in nutraceutical development: that successful ventures are those in which three sectors—food ingredient, food processing, pharmaceutical—are represented. This statement parallels the current and ideal strategic alliances described previously in this report.

49. Having discussed the range of words available, and the type of nutraceutical activity prevalent in Canada, which of the above words, if any, are most appropriate for Canada and why?

Twenty-eight, more than 60% of the respondents, did not answer this question. They either, "Couldn't say," or did not have a preference or liking for any of the words in the lexicon.

The majority of the remaining respondents preferred the word nutraceutical, offering the following reasons when they could:

- That's the word I hear most often and it's becoming quite common.
- Nutraceutical has a scientific back up [connotation].
- Nutraceutical is just right due to treatment of disease.

Functional foods was preferred by four respondents, who provided the following reasons when they could:

- It connotes a food rather than a drug.
- Nutraceutical defines what it is but functional food is better for the consumer.
- The connotation ties in the, "It's good for me food," rather than, "It's a drug."
- Use words which are non-drug like. Drugs (...'ceuticals) show that people are sick. Give them good food which keeps them healthy.

Two other terms, designer foods and health foods, were offered; the reasoning was that consumers understand these terms; one must include the word food for consumers to, "Click."

Although nutraceutical and functional foods are the most commonly used terms, few of the respondents actually like these words when describing foods with health claims. The majority of the respondents are using the words, yet would not agree they are the best for Canada. The common denominator in the reasons given for preference was consumer response and understanding. It appears from these responses that none of the words in the lexicon is appropriate for Canada.

50. Is there another "new" nutraceutical word appropriate for Canada? If so, what may this word be that truly represents the type of activity taking place here?

Only five respondents ventured to answer this question. Of these, two felt that nutraceutical was appropriate. One believed, "this word is selling" and the second felt that, "the consumer has to understand this whole thing and this word is understandable." Two respondents had quite novel thoughts on this subject, offering the following points:

- I'd like to see a new word but it needs to be bilingual.
- Canada has value as a marketing name. A catchy word that implies health and disease prevention at the same time is needed.

The reluctance of the respondents to offer a new word, and the lack of agreement among them regarding the current lexicon, suggests that Canada develop a new word for foods with health claims. This is further supported by the fact that the most widely accepted definition of nutraceutical includes the treatment of disease. This Canadian nutraceutical study reveals that current Canadian nutraceutical activity is focused on prevention of disease and modulation of risk factors. On the other hand, consistency in the terminology used in the international marketplace is an important consideration.

Strategic action plan

51. Can you briefly identify, if possible by order, the necessary strategic steps required by industry to realize a nutraceutical industry in Canada?

Twenty, or almost half of the 45 respondents, identified working with and collaborating within the industry and with the federal government towards regulatory reform as the dominant strategic step required in the nutraceuticals area. Many felt that an industry association or lobby group should be established. Comments were as follow:

- Avoid adversarial relationships. Work as an association, take a stand, mesh with Health Canada's mandate.
- Put together an expert panel to champion the cause.
- We have the manpower and intelligence to make it a powerful category. Put together a team effort to confront regulatory barriers.
- Form a separate industry lobby group; focus on changing the regulatory environment to include nutraceuticals. Show the economic advantage of nutraceuticals to the Minister of Finance.
- Stop trying to maneuver around the barriers; fight to change the legislation.
- The government is moving towards regulatory reform.
- Agree on the levels of clinical testing and toxicity testing. Give the government that input and let them work with it.
- Work with protocol standards.
- Develop a consensus on how to deal with targeted public health issues through nutraceuticals.

The second most commonly mentioned strategic step was education of the consumer. Those who made this recommendation believed:

- It is, "Industry's responsibility to raise public awareness, crystallize the demand, and let the consumer know you have answers to their problems."
- Without consumer education, the consumer will not realize they can improve their health without resorting to drugs.
- Without education, there will be insufficient demand to make the venture worthwhile.

A close third in terms of frequency of mention, was the funding of research and collaboration with academia. The following comments made in the survey illustrate this:

- Fund research programs to get the scientific data to back the claims.
- There are tough questions out there so line up your scientific information to go up against the quacks.
- Develop protocols and define the scope of research to address certain issues.
- Form joint ventures with the universities.

One specific comment from an ingredient supplier was directed at the grocery industry. The suggestion was to drop listing fees for Canadian products and, conversely, increase listing fees for non-Canadian products.

The dominant strategic step for industry, as shown in this survey, is to work with the federal government towards regulatory reform. Consumer education to crystallize a market and the furthering of research were also frequently mentioned.

52. Can you briefly identify, if possible by order, the necessary strategic steps required by the federal government to realize a nutraceutical industry in Canada?

Twenty, or almost half of the respondents, recommended that the federal government provide a set of regulations which allows specific health claims on food. Comments in support of this recommendation included the following:

- Implement fair but strict legislation, accept this concept and trust it.
- Review the regulatory change in Japan and then re-assess [their] position domestically.
- Develop a process to justify the claims in which the public has confidence.
- Provide a sensible set of regulations.

The next most commonly recommended strategic step for government was to recognize the potential value of nutraceuticals in decreasing escalating health care costs.

The remaining comments were quite fragmented. However, funding of research was mentioned a few times, as was striking alliances with both the private and academic research community.

Just as the first strategic step for industry was to work towards regulatory reform, this was also regarded as the first step for government. It was suggested that they conduct international reviews and then re-assess the domestic situation next to international standards. The second suggestion, that government recognize the potential role of nutraceuticals in reducing national health-care costs, may provide the incentive to bring about the first step. Thirdly, funding of and/or participating in clinical research received numerous mentions.

53. Can you briefly identify, if possible by order, the necessary strategic steps required by other sectors of Canada to realize a nutraceutical industry in this country?

There were two commonly mentioned required strategic steps, one for educational institutions and the other for the research community.

It was recommended that information about nutrition and health benefits associated with nutraceuticals be incorporated into Canadian educational streams ranging from elementary schools to business schools, to medical colleges. The view was that the public can be made aware of alternative food (and nutraceutical) choices that could, ultimately, reduce the health care-cost burden on the system.

It was recommended that the research community be selective in research projects, choosing those that meet the needs of industry and maximize the potential of Canadian agricultural crops; practice leading-edge scientific research; promote research achievements in the media; and develop centers of excellence.

Additional comments

54. Do you have any comments you wish to add which you have not had the opportunity to?

Few respondents had additional comments, saying that they found the questions to be interesting, thought-provoking, challenging and a thorough coverage of the nutraceutical concept/opportunity.

Findings of Survey in Comparison to Literature Review

The survey results both concur and differ from the results of the literature review.

1) Various challenges and dilemmas posed by nutraceuticals were revealed in the literature review. The survey respondents regarded nutraceuticals as an opportunity, with little mention of the hazards or challenges as described in the literature. Hence, the respondents may be either unaware of these challenges ahead of them or are undaunted by them.
2) The secondary literature positioned the pharmaceutical industry as playing a role equal to that of the food industry in the nutraceuticals area. This survey did not accord, suggesting that the food industry as the major player. The reasons for this difference may be as follow:
   - The secondary data was largely American, where pharmaceutical companies have large research laboratories and facilities. "Most active ingredients in pharmaceuticals sold in Canada are imported." (Pharmaceuticals Industry, Science and Technology Canada Industry Profile. 1992, p. 2)
   - A Canadian branch plant may not be free to develop a nutraceutical because it might compete with or "cannibalize" the parent company's export revenue from active ingredients.
   - Three high profile researchers in this survey claimed that all pharmaceutical companies are involved, but in a clandestine fashion, adding that [they], "are working behind closed doors because they know their days are numbered."
   - It should be noted that there were only three pharmaceutical companies included in this survey, and it may be that they did not want to share information regarding their alliances or research. Further, as most of their research is likely to be done abroad maybe Canadian respondents were not fully aware of these activities.
3) The literature revealed that strong industry alliances exist, most commonly between food and pharmaceutical companies. The survey, on the other hand, suggested that strategic alliances in Canada tend to be loosely defined, at their beginning-stages, and are primarily between food-ingredient companies and manufacturers. Clinical research in Canada seems to be most-often provided by an academic institution, although it may be supplied by a pharmaceutical company as well. In contrast, the "ideal" Canadian strategic alliance, as suggested by the survey respondents, would include some sort of pharmaceutical support.
4) "Nomenclature chaos" has emerged in the U.S. and European markets, generating confusion as, "Every name has a different connotation." During this beginning stage of the nutraceuticals industry in Canada the practitioners are experiencing what could be called "nomenclature inertia." They do not like the current lexicon, but have yet to discover a word that accurately conveys the benefits they believe to be present.
5) Nutraceuticals and functional foods are positioned in the literature as either treating and/or preventing disease. Current nutraceutical research in Canada, as well as the direction of the nutraceutical market, is focusing on the modulation and management of risk factors as a means to, at the very least, abate and, at the very most, prevent disease. It is this definition which seems to be seeking a Canadian moniker.
6) The literature review showed that there have been strong appeals for: 1) regulatory controls on health claims for food, and 2) consistent, well-designed and rigorously executed clinical

trials. Seemingly, health claims on food are rampant in some countries. This is most true of those countries where consumer acceptance stemming from cultural traditions and folklore is so strong that the regulatory bodies cannot curtail it, with or without scientific backing. Such is not the case, for the most part, in Canada where, as the survey suggested, the health claims on food need leniency, not tightening. Concurring with the literature was the appeal among those surveyed, for sound science and excellent research and testing protocols. It was felt that these should be required in Canada, for the most part, to permit regulated health claims. Some respondents strongly believed that fair regulations would also eliminate unscrupulous health claims. In some countries and in some situations, science is required to control heretofore unsubstantiated health claims.

7) The literature review includes references to the application of the Health Canada guidelines for validating statistically the laxative efficacy of novel fibers. Perhaps these guidelines could be applied to other food substances, leading to permissible health claims.
8) The literature alluded to three dominant barriers to the marketing of nutraceuticals: restrictive regulatory climate, the cost of clinical trials and the difficulty in obtaining patent protection. The survey identified three dominant barriers: restrictive regulatory climate, lack of sound science and scientific protocol, and the cost of clinical trials. The major difference is the Canadian request for better science. It could be that Canadian researchers and manufacturers are not satisfied with the quality of science reported in the literature and either seek a more rigorous protocol or sense that such is required to obtain regulatory approval.
9) Even after a review of over 100 articles related to the nutraceutical market, market size remains nebulous. Such is true in Canada also. Market size can be measured in terms of units and/or dollars. However, both size and value are strongly affected by the regulations. The potential market for nutraceuticals, both in Canada and internationally, is immense, largely because of the range of ingredients undergoing research and development, and the will of the industry to exploit market opportunities associated with the potential benefits of these products.
10) According to the literature, determinants of the nutraceutical industry are: attempts to mitigate escalating health care costs, a growing awareness among both consumers and physicians of the relationship between nutrient intake and disease, and regulatory approval of health claims. The survey results showed that the determinants of a Canadian nutraceutical industry are: consumers' demand for quality of life, free of drug dependency; industry and research responsiveness to this demand; and regulatory approval of health claims. The literature and survey results thus concur on the aspect of market determinants/deterrents.

Conclusions and Recommendations

1) All stakeholders should recognize that Canadians are increasingly expecting health benefits from food. They are traveling to countries where food-health associations have been made for thousands of years and they bring this experience back to Canada with them. Canadians are also becoming more closely associated with people of Asian cultures. Increasingly, Asian ethnic groups are increasing in size in Canada. The increase in the number of Asian immigrants to Canada is not only influencing Canadian habits but creating a diversified

market. In their traditions and folklore some of these cultures have long recognized the medicinal value of food ingredients, especially herbs. Furthermore, in-part because the large baby-boomer segment of Canadian society is aging consumers are becoming increasingly knowledgeable about and conscious of health, nutrition and the role of diet in preventing or mitigating the onset of disease. More and more this attitude is being reflected in people's choices.

2) Stakeholders should consider establishing a nutraceuticals (functional foods) advisory group or association composed of representatives from the food ingredient sector, food manufacturing sector, academic research community and, if possible, pharmaceutical sector to work with the federal government. Agriculture and Agri-Food Canada could, perhaps, facilitate the coordination of such a group and Health Canada could be involved from the regulatory side.
   - A primary objective would be to bring the appropriate regulatory agencies (food and drug) together to discuss the issues and options for change. The group could also determine what scientific evidence is required to bring about regulatory reform that facilitates the recognition of the disease-preventative attributes of nutraceuticals. It would be important for the association to collaborate with the Health Protection Branch towards changing the *Food and Drugs Act and Regulations* in some way, both to permit bona fide health claims associated with nutraceuticals and eliminate unsubstantiated claims.
   - Another goal of the group would be to find ways of reducing the cost of clinical trials or ways in which the cost could be offset by government through policies and programs.
   - A third goal could be to adopt a multisectoral communication strategy to build awareness with respect to the role of Canadian nutraceuticals in disease prevention and enhancing the quality of life.
   - This group would have to be selective, strategic and focused. For example,
     - To position nutraceuticals as an avenue for reducing escalating health care costs, it could attempt to calculate the cost of health care attributable to those chronic diseases that can be abated with nutraceuticals of Canadian origin. A good illustration is Japan, where FOSHU was legislated to halt rising health care costs; although, it is, perhaps, too soon to know whether it has been successful in this regard.
     - The group should target the mitigation of those chronic diseases that have the greatest impact on health care costs.
     - In addition, it should emphasize those Canadian agri-food crops that have the strongest nutraceutical potential and commercial value in both domestic and international markets.

3) It has been shown that investment is being made in research and development of nutraceuticals in Canada, and strategic alliances are being formed in the food ingredient sector, food manufacturing sector, and academic research community. An even greater emphasis on these activities by stakeholders and the agri-food network could lead to a greater return on investment through commercialization of more nutraceutical products, and sales of greater volumes of products in more markets.

4) Stakeholders should continue to discuss appropriate terminology for the nutraceutical category, to ensure that it connotes foods or food ingredients that mitigate disease through the

modulation or management of disease risk factors. The terminology used in the international marketplace is an important consideration.

5) Stakeholders should recognize the integral role to be played by health-care professionals including nutritionists, dietitians, home economists, public health nurses, physicians, and alternative practitioners such as chiropractors. Perhaps a survey of these professionals could be conducted to get an idea of their attitudes towards nutraceuticals. However, perhaps the nutraceuticals market in Canada should be more firmly established first.

Appendix 1: Literature Review

This literature review is more of a compilation of information rather than a review. The sources were extremely varied. Much of the information has been extracted directly from the articles referenced.

A nutraceutical can be defined as any substance that may be considered a food or part of a food that provides medical or health benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, products of biotechnology and dietary supplements, to genetically engineered "designer" foods, herbal products and processed foods, such as cereals, soups and beverages. (21)

The Foundation for Innovation in Medicine coined the term "nutraceutical" in 1989 to provide a name for products resulting from this rapidly growing area of biomedical research. The term has since become part of the standard lexicon in both the medical and scientific communities, and in the food and drug industries. (21)

The concept embodied in the term nutraceutical—disease control by diet—gained momentum in 1991 after the International Conference on Nutrition and Cancer in Atlanta, Georgia. (81)

Wood (93) writes, "The underlying rationale for producing [nutraceuticals] is that many of the diseases of industrial, developed societies are life-style related, with diet playing a major role. The conditions take many years to develop and prevalence therefore increases with an aging population. Once established, the illnesses are expensive and difficult or impossible to treat. Diet-related disease is therefore an enormous social and financial burden on modern society. The most effective way to deal with these worsening health care problems is prevention, in which improved diet would be a key element."

The development of nutraceuticals is international in scope. The role of dietary factors in the prevention of major chronic diseases, cancer in particular, is under intensive investigation by many laboratories around the world. (12)

The range of potential nutraceuticals spans the entire food system. ..."from exotic mabuang, used in China to treat asthma for five thousand years, to the humble cabbage, which has been effective against stomach ulcers in clinical tests." (65) However, their inclusion in traditional medicine as we know it in 1995 will not be without some hesitation, as phrased by Mark Blumenthal in his foreword for Penelope Ody's book, The Complete Medicinal Herbal: "No doubt the author's statements and recommendations will raise a few eyebrows among conventionally trained pharmacists or physicians....Yet as herbs and other alternative forms of natural healing are increasingly sought after by an interested lay public, it becomes incumbent upon health professionals to approach new and old therapies with an open mind." (65)

Tertiary function of food

Over the past 10 years foods have gained an extra dimension—something beyond being delicious and nutritious. This extra dimension is a specific physiological response produced by some foods; hence, the term "physiologically functional foods," or PFF. Foods claimed to release

stress, for example, lower cholesterol, boost the immune system, antagonize cancer, or aid brain function can all be listed in this category. (38)

Foods have three purposes. In addition to maintaining life and providing sensory appeal, "functionalized foods" have a tertiary "body regulating" function to prevent, cure or assist in the recuperation from disease. (45)

The Japanese have identified the biological advantages of functional foods. In addition to body-protecting and disease prevention, other functions include disease recovery, body rhythm regulation and reducing the effects of aging. Claims relating to these tertiary functions [are legally permitted] and follow a model statement along the lines that "one who takes this product for the specified health-keeping purpose is expected to get the desired effect."

There are four types of nutraceutical products (49a):

1. genetically-engineered foods, e.g., enhanced tomato
2. raw food, e.g., carrots that contain beta carotene
3. processed food without added ingredients, such as oat bran cereal
4. processed food with added ingredients, e.g., calcium-enriched orange juice

Nomenclature / terminology

A plethora of terms, used interchangeably with nutraceuticals and described by one as "nomenclature chaos" (21) has emerged. A representative of one prominent company in this industry has noted that every "name" has a different connotation. (Pfizer from 38)

Pitts (69) reports that "functional foods" is the most common term in the EU. He expects it may be overtaken by the American term "nutraceutical" which he believes appears to convey the concept better.

Dr. Nancy M. Childs, Ph. D., Professor of Food Marketing, St. Joseph's University, the most exhaustive researcher to date on the emerging American nutraceutical industry reported more than 16 terms currently used interchangeably to describe "nutraceuticals". These 16 terms are shown below. I have added another one, parnuts, on the bottom in italics. Parnuts is used in Germany to denote "foods for particular nutritional uses".

- medical foods
- nutraceuticals
- functional foods
- nutritional foods
- pharma-foods
- designer foods
- fitness foods
- therapeutic foods
- superfoods
- longevity foods
- pharmaceutical foods
- prescriptive foods

- nutraceutics
- medifoods
- foodiceuticals
- pharmaco-Foods
- *parnuts* (German)

There appears to be a vernacular emerging in some industries, as evidenced by Dr. Childs' findings (16):

1. 61% of the pharmacy industry used or were familiar with "medical foods"; 59% with "nutraceuticals"
2. 55% of food and biotechnology firms were familiar with "functional foods" (a Japanese term)
3. 52% of food and pharmacy companies were familiar with "nutritional foods"

Thus, it is not surprising that some professionals encourage one common name to facilitate industry growth, induce regulatory governmental policy and to encourage research in the field. (16, 91)

Current status of diet/nutrient-disease associations

R&D in the area of diet and health is shifting from studies of the adverse effects of high amounts of [some substances] to the beneficial effects of natural antioxidants, preservatives, and biologically active phytochemicals as nutritional supplements for disease control. (80)

This concept will raise the health threshold of many food and drink products. Promotion and communication will switch from what a product doesn't have, e.g., cholesterol, to what the product does have, will do, e.g., such as help prevent cancer. (70)

Nutraceuticals, because they prevent and treat disease, will compete with both drugs and foods by the year 2000. (24) In the early 1980's, the potential medical benefits of calcium, fiber and fish oil rose to prominence due to the support of university-based clinical data. For the first time in modern American medicine, physicians joined consumers in their broad belief that nutrients have medical value.

The literature revealed numerous studies drawing a correlation between nutrients and diet control. Some are based on clinical studies; some on epidemiological observations. It is interesting to note that most of these studies made no mention of the term "nutraceutical" or any of its synonyms.

Examples of nutrient-disease relationships with clinical studies

Designer foods

The National Cancer Institute (NCI) is an American leader in the pursuit to understand how fruits, vegetables and grains may control disease. The NCI's Diet and Cancer branch has embarked on a five-year major initiative to study, assess and develop experimental or "designer" foods, described as "processed foods that are supplemented with food ingredients naturally rich in cancer-preventing substances". (12)

The NCI's "Designer Foods" initiative is intended to provide new clinical insights into the relationship between fruit, vegetable and cereal consumption and the physiological and biochemical processes that lead to tumor formation. The concept that "phytochemicals" can play a role in the prevention of cancer can be extended to include other chronic diseases as well. (96)

Antioxidants

Antioxidants and their potential role in repairing the accumulative damage of daily oxidation of human body cells are being studied vigorously. (4)

Biochemical studies indicate that oxidative damage contributes to the causation of several major degenerative diseases, such as cancer; cardiovascular disease; cataracts. Compelling scientific evidence and a rapidly increasing body of epidemiological evidence indicates that three major antioxidant nutrients – vitamin C, vitamin E and Carotenoids – play crucial roles in preventing or delaying the onset of these diseases. These dietary antioxidants are rich in fruits and vegetables. When expressed in terms of relative risk, 132 of 170 studies showed statistically significant protective effects. However, the current diets of most Americans are shockingly low in fruits and vegetables; dietary intakes of specific antioxidant nutrients are also low.

Lignin and breast cancer

University of Toronto research suggests that a compound found in flaxseed may either retard or slow the growth of cancerous tumors. Flaxseed, also called linseed, is present in milled form in some breakfast cereals. Dr. Lillian Thompson and her research team screened 66 different plant foods for lignin, or lignin-like compounds that the body can convert into usable lignin. Flaxseed was seen to be the highest source, containing 800 times more than any other plant food in the diet. In studies conducted on rats, the group found that lignin can reduce the rate of breast-cancer tumors by as much as 50 per cent.

The researchers were quick to acknowledge the role of the entire diet:

"Researchers are clearly interested in identifying compounds in foods that could be used in the treatment of cancer as well as other diseases. But the real beneficial effects might be in the way these compounds react with each other in the body. And that means that total diet, rather than its individual parts, is important to overall health."

...However, much of this research is in preliminary stages and is unlikely to translate soon into new and widely available cancer treatments. (88)

Citrus limonoids

Citrus Limonoids are one of the two main classes of compounds responsible for the bitter taste in citrus fruits. Recently, it has been determined that citrus limonoids have certain biological activities that may be used as chemopreventive agents. The cumulative effects of citrus limonoids on cancer prevention remain to be determined. (52)

Citrus compounds

A large number of epidemiological studies show that citrus fruit consumption is protective in a variety of human cancers. It is assumed that most, if not all, of this protective effect is due to

vitamin C. Seven citrus compounds were tested for their oral cancer-preventive activity. However, in several of these studies, the authors have compared citrus fruit consumption to vitamin C intake. Their findings suggested that the frequency of consumption of citrus fruits was more closely linked to risk reduction than vitamin C intake. This suggests that citrus fruits contain not one but multiple cancer chemopreventive agents. (60)

Citrus flavonoids

Several health-promoting properties have been ascribed to the flavonoids on the basis of in-vitro and animal studies. (59) For example, the citrus flavonoid tangeretin may inhibit the processes that shorten the life expectancy of tumor-bearing patients. (72)

Various antioxidants

Beta carotene, vitamin C, and folic acid may provide protection against cancer, heart disease, and neural tube defects. (6)

Pectin and pectin-fiber

Citrus pectin or pectin-fiber mixtures may improve glycemic control and reduce serum cholesterol levels. (1)

Carotenoids, antioxidants and visual impairment

Increasing the consumption of foods rich in certain Carotenoids, in particular dark green, leafy vegetables, may decrease the risk of developing advanced or exudative AMD, the most visually disabling form of macular degeneration among older people. (75)

Previous studies have demonstrated that two specific carotenoids, lutein and zeaxanthin, form the yellow pigment in the macula, the central area of the retina; these Carotenoids absorb blue light and thereby may prevent photic damage to the macula. This observation lends biological plausibility to the finding by Seddon et al that higher dietary intakes of lutein/zeaxanthin are strongly associated with a decrease in risk of AMD. (47)

A Canadian study found lower cataract rates in users of vitamin C or vitamin E supplements than in non-users (Robertson, J. M., Donner, A. P. and Trevithick, J. R. 1989. Vitamin E intake and risk of cataracts in humans. Ann. N. Y. Acad. Sci. 570: 372-382.) (75)

Tomatoes and cancer

During digestion the body routinely makes compounds, called nitrosamines, (potentially carcinogenic) from nitric oxide and amino acids. This study showed that tomato acids grab hold of nitric acid and whisk it out of the cell before it is united with the amines. The mechanism is owing to two of tomato's 10,000 phytochemicals, called p-coumaric acid and chlorogenic acid. It was found that tomato juice was more effective than just the vitamin C component. (19)

Examples of nutrient disease relationships without clinical studies

There are two major groups of natural protective substances that can be used as fortifiers [for functional foods]: one group includes substances that have already been identified as helpful in

preventing disorders such as fiber, and the other group includes those substances still in the research stage. Once the substances in the research stage are identified in fruits, vegetables, grains, spices, herbs, caffeine and tea, it may be possible to extract them for use as fortifiers, to be used like drugs that prevent or treat diseases. Some of them have been part of herbal and folk medicine for generations. If successfully identified, extracted and approved, tomorrow's consumers will have a painless, effective, low cost treatment available to them. A public health service would be provided. (8)

Discussed below, are examples from the literature of substances still in the research or observation stages:

Broccoli sulforaphane and cancer

How sulforaphane in broccoli may work: Cancer can begin with a carcinogenic molecule invading a cell. (If biologists have learned anything over the next few years, it is that disease is a multistep process). Within hours after being eaten, sulforaphane enters the blood stream. It circulates and triggers one of the body's defense systems. When sulforaphane reaches the cell, it activates a group of proteins called phase 2 enzymes. The enzymes burst into action, attaching the carcinogen to a molecule that whisks it out of the cell, headed for oblivion. The mechanism seems to keep lab animals from getting breast cancer. (2)

Nutraceuticals from dairy products

1. conjugated linoleic acid: has antioxidant and antimicrobial properties and shows anticarcinogenic activity in vivo
2. lactoferrin: antioxidant activity, highly bioavailable iron source and acts as a bacteriostate
3. lactoperoxidase: antimicrobial properties

(from 37)

Canola oil and cancer

..."Biologists at the University of Calgary see genetically altered canola as an inexpensive and relatively painless alternative to chemotherapy. They hope to develop, in the canola seed, a protein-like string of amino acids that will stimulate the growth of antibody-carrying white blood cells. [...] As a result, it has become extremely popular with those who have made the shift to healthier diets. The oil derived from canola is lower in saturated fats than safflower or sunflower oil, lower even than olive oil, if not as tasty." (71)

Miscellaneous

Other areas of interest are: Vitamins ACE as antioxidants; antimicrobials from nutmeg and bay leaf; antioxidants from rosemary, oregano, clover and sage; green tea polyphenols and bifido bacteria-promoting food compositions. Thus, emergence of a new functional processed food category is inevitable. Twenty-seven U.S. patents were issued in 1990-1991 on natural antioxidants and preservatives, with extracts from herbs and spices being most numerous. (19)

Appeals for regulatory and efficacy-claims controls

There appears to be a concern for a kind of chaos in addition to "nomenclature chaos", which I'll term "claim chaos".

There are numerous appeals in the literature for the health claims associated with food and nutrients to be not only the result of strict, rigorous, scientific clinical trials, but also, regulated by a government body. Peter Wood, of Agriculture Canada, phrased the dilemma quite adequately in an internal memo: "The issues are difficult, in that our knowledge of human nutrition is inadequate and consequently the proposition that we can improve health by consuming specific foods has the corollary that we can similarly damage our health.[..] The potential for unscrupulous exploitation is great." (93)

Appeals for clinically proven efficacy

Government-approved health claims on food are not new. Historically, they have been based on scientific evidence. For example, Cream of Wheat, in 1939, came out with an "enriched" porridge that had more calcium, iron, vitamin B, niacin and phosphorous. The product made its debut only after seven years of intensive research that gathered opinions from the nation's leading physicians. (38) The same was said of Wonder Bread in 1941 when Continental Baking joined the government-supported bread enrichment program, which brought essential nutrients to consumers who could not afford a wide range of nutritious foods. The result was virtual elimination in the U.S. of the diseases beriberi and pellagra. "Wonder Bread helps build strong bodies," is a marketing classic. 65

One source of the concern about unsubstantiated or weak health claims on food is the observation that some food companies are relying on consumers having read or heard about the latest health study. The food industry links a new product with public relations efforts to ballyhoo a study that suggests a health benefit. It is left to consumers, looking for less-invasive health remedies, to connect the two. Clinical trials are a key to this industry, but there have been health claims based on inconclusive clinical data. (16)

Ms. Rosemary Stanton, speaking on functional foods and their future in Australia makes reference to an overly-aggressive food industry, cautioning that "we should be humbled by the recent discoveries that our knowledge of fats and cholesterol is still at an elementary stage. We have only just realized how little we know about human nutrition. More than 600 different compounds have antioxidant potential. However, many researchers have seized on the few antioxidants with which they are familiar. [...] We do not know the ACE vitamins are necessarily responsible. They are just three among hundreds of antioxidants found in fruits and vegetables. Yet on this basis, without enough knowledge, there is a move to encourage food manufacturers to produce functional foods with high levels of ACE vitamins. This is jumping the gun. ACE vitamins are not the most potent antioxidants and, with beta-carotene, may even interfere with the absorption of other nutrients". (85)

Caragay (12) warns that the size and complexity of the challenge must not be underestimated. In addition, the claims/efficacy issue has attracted a great deal of attention and is being aggressively discussed and debated with different authorities varying in their opinions and policy. Many

manufacturers are waiting to ride the wave once the confusion and inconsistencies have been resolved.

One paper cited collective efforts being made between government regulatory authorities, the manufacturing industry, dietitians, nutritionists, microbiologists, biochemists, food scientists and consumer protection groups to assess these products. Such attempts are being made in Japan, U.S. and Europe. (38)

A report of various distinguished scientists debating this very issue quoted one researcher as stating that health claims for one group [of food] is a Pandora's Box. If one kind of psyllium lowers cholesterol, you can't assume all psyllium will. (30)

In the same paper, Dr. David Jenkins of the University of Toronto cautioned against the implication that nutrients can control disease. Dr. Jenkins reviewed the experimental evidence from controlled human studies on the relationship between dietary fiber and Coronary Heart Disease (CHD) to find that not one single positive study could be found. There have been studies, however, on the link between CHD surrogates such as cholesterol, blood pressure and clotting factors.

Dr. Jenkins stated that should health claims be allowed if there is sufficient evidence, they should also require "the usual general statement about the [necessity of the] entire diet. I don't want to see claims for fiber independent of the dietary pattern". Dr. Jenkins cited a concern about fiber supplements as many scientists said they cannot predict what will happen when fiber is removed from the "material matrix". Collectively, the scientists voiced a need for greater research to rectify the current problem of lack of consistency among clinical trials. (30)

Caragay (12) has made an appeal for scientists to demonstrate what, if any, are the specific and quantifiable health benefits that can be claimed for particular foods. This approach is also needed to protect consumers from false or misleading claims

A Canadian clinical researcher predicted that foods which are protective, to a certain degree, against modern illnesses, will be in high demand. However, he is both cautionary and encouraging when he states that sorting out fact from fiction by providing hard scientific evidence remains a major challenge to the scientific community, yet a challenge worth taking, for these are the foods for the future. (39)

Writer Ralph Blanchfield writes: "In an era of increasing recognition that the relationship between diet and health is more than merely to sustain life, there is growing interest in the way in which foods and food substances help to maintain food health by many of the public, by scientific researchers, by industry perceiving a market for such foods, but also by charlatan and "fast buck" operators who see a fruitful opportunity to cash in, using false or misleading or unsubstantiated health claims. It is to protect the public as far as possible from these claims, as well as to safeguard public safety, that the need for regulatory control is recognized, and not just by regulators but by scientists who are experienced in this area. The need to be able to demonstrate the safety and efficacy of products for which health claims are made cannot be dismissed cavalierly. Some substances with real or supposed health benefits may be dangerous when ingested at high levels (e.g., mega doses of vitamins A and D). (3)

Herbalist Mark Blumenthal writes "that if herbalists expect to have their craft accepted by mainstream medicine and the public, they must be willing to rely on information from scientific and medical domains". (65)

The crux of the matter for both the food industry and the pharmaceutical industry, is the difficulty in obtaining clinical evidence of efficacy. Companies will resist devoting R&D funds to nutrition research until they have a proprietary right to use the resulting claims. It is suggested that large multinationals will dominate this market segment and that a large number of joint ventures between pharmaceutical and food companies will be formed. (5, 64)

Issues in research and guidelines for research

Clearly, protocols for nutraceutical clinical studies need to be designed. Jenkins (44) identified numerous unresolved issues in functional food studies:

1. guidelines governing the execution of studies
2. experimental design
3. test substances and compounds
4. stability, homogeneity, and acceptable levels of the test substances
5. assessment of compounds in the diet for control of nutritional and other dietary variables
6. preparation of animals for euthanasia
7. statistical evaluation

The Journal of the American Medical Association wrote an Editorial on this topic, entitled, "All that Glitters is not Beta Carotene"..."Not all antioxidants are created equal. The substantial differences in the structure and biologic properties of specific antioxidants are likely to influence their ability to prevent a specific disease. Therefore, a null finding for one antioxidant on disease risk does not mean that other antioxidants could not be effective. Beta carotene (has been) the primary focus because it was the best known antioxidant due to its potential vitamin A activity. Finding an association depends on giving the appropriate nutrient, in the appropriate dose, for an appropriate period of time, to an appropriate population. Failing to meet any one of these requirements will reduce or eliminate the probability of finding an effect even if one exists." (47)

There have been several general concerns raised about the interpretation of at least one type of functional food study, such as the designer foods studies. (50) These include:

1. the contradictory effects of a particular phytochemical on a given disease
2. the contradictory effects of a particular phytochemical on various diseases, e.g., one can increase risk of one disease while decreasing risk of another
3. isolating food chemicals from their natural environment may separate them from substances that enhance or reduce their true effects
4. the danger of creating a magic "cure-all" food — rather designer foods must be viewed as supplements to a balanced, healthful diet and lifestyle

A call is heard for research which identifies the most potent compounds, determines optimal intakes, determines the mechanisms of action, and, assures safety. Such studies should include carefully designed human feeding trials, the results of which must be interpreted with caution.

The resolution of these issues will involve interaction and collaboration among university, government, and industrial laboratories.

While the scientific community is considering and debating the criteria for adequate protocol, one regulatory body, the FDA, has identified six top criteria to consider when evaluating diet-disease relationships (97). These, taken verbatim, are as follows:

- Strength of association
- Dose-response relationship
- Temporally correct association
- Consistency of association
- Specificity of association
- Biological plausibility

Appeals for regulatory control

That the FDA has taken steps to identify such criteria is an encouraging sign. The regulatory restrictions on health claims are regarded as a major barrier to the evolution of the nutraceutical industry. (16)

The dilemma occurs when a governmental body is regulating safety versus regulating a benefit. As a result, foods have been developed which pose no safety risk but are unable to present health claim information without being regulated as a drug. (48)

Japan has already established a system for approving nutraceuticals and has taken the lead in the world race to patent plant-derived products. Major European countries now have systems that grant exclusivity for innovative medical and health claims for nutraceuticals based on proprietary research, and procedures to grant exclusivity throughout Europe have been developed by the EEC. (22)

Due to the need for clinical research, there is an equal need for proprietary rights. Dr. Stephen DeFelice cites an "obvious solution" – to establish an updated economic and regulatory system that serves the public interest and matches today's scientific and medical reality. This process is beginning to evolve in most industrialized countries outside the U.S.. (22)

Regulatory status on health claims in Japan

Japan is the international leader in the area of nutraceuticals. In Japan, this category of food is called "FOSHU" or Foods of Specified Health Use.

As of April 1995, 24 FOSHU food products have been approved for licensed health claims by the Japanese Ministry of Health and Welfare. The claim can only made by a license holder. The license includes details such as the brand name, common name, applicant, type of food, the functional component, and the health claims, plus the date of the license. (43)

The concept of FOSHU, that is, food which, from the scientific aspect, is expected to be effective in preventing disease, came up in the latter 1980s. From the latter 1980s to the present, a large variety of this type of food has been put on the market, although it did not receive a separate classification. They have since been included in the Food for Specified Health Use. (45)

Diseases such as heart disease, diabetes and cancer are a growing problem in Japan due to a rapidly aging population and the Westernization of diets. National medical expenditures in Japan have increased 14 fold over the 25 year period from 1967 to 1992. (63)

The future of FOSHU in Japan is expected to be bright. Present trends visible in Japan are an increase in the consumption of healthier foods, an increase in the elderly population, a switch from the treatment of disease to the prevention of diseases to reduce medical expenses, an increasing number of sales outlets, and changing distribution channels of health-oriented foods, all of which bode well for this market in Japan. (45)

"Private industry is actively engaged in R&D in the prevention of diseases. Currently, as many as 28 active ingredients are being researched for their effect on a number of physiological functions as well as their bioavailability in different forms of food.

What can be learned from the Japanese

As one industry professional put it, "Correlate the Asian success." (38)

Japan has taken the lead in the area of foods for disease prevention. Japan not only allows but encourages the use of functional foods as a way to reduce the burgeoning health care costs of the nation. (13)

There is a nine-year history leading to materialization of FOSHU in Japan in July 1991. As the Japanese put it themselves, (35), the cultural background for FOSHU is their mutual common sense and historical belief that natural substances hold an important key to preventive and therapeutic advances. In addition, recent scientific studies on the role of various food components have revealed a great deal of evidence to support this. And finally, the Japanese Government legislated FOSHU in order to avoid any confusion over the growing array of new products and developments falling outside the traditional concept of either a food or a drug.

It is important to emphasize that a very special cooperative [effort] was instrumental in fostering the FOSHU concept in Japan. The Government was interested in medical care cost reduction; academia in new research; and the food industry in new business opportunities. This resulted in collaboration and consensus, each with its own stake of interest.

According to one analyst, the economic effect of FOSHU may reach as much as US $8 billion within a couple of years. This [overall structure] is essential for the government to reduce the health care cost expenditure which is estimated to reach more than US $540 B in the year 2010.

Another author predicts the Japanese cost of medical treatment and medicines to peak in year 2025 at US $1.120 T, adding that this should be reduced by encouraging the population to eat more foods which can provide positive health benefits. (79)

It has been heavily emphasized that FOSHU is a food—not an isolated nutrient—which has strongly suggested health benefits based on sound, scientific research data. The key is to educate consumers so they know the intakes of individual food components and thus, they will be able to design their healthful diet based on sound data and proper labeling.

The Japanese Government may introduce a new system so that only stores with a FOSHU certified nutritionist can sell FOSHU labeled products.

Most of the specific food component claims are based on principles familiar to American scientists. However, Japan has moved more slowly than first expected. "They appear to want to be sure that sound science supports the health claims." (45)

It is interesting to note the elements of FOSHU's success. Their common sense and cultural background, combined with scientific principles and discoveries, indicated that FOSHU was possible. The one clear overall objective is to reduce health-care costs, and their modus operandi is consensus building and collaboration.

Regulatory status on health claims in the U.S. and Canada

The sale of foods and drugs in both Canada and the U.S. are governed by legislation. In Canada, the applicable act is the *Food and drugs Act and Regulations*, administered by the Health Protection Branch of Health Canada. In the U.S., the activity is governed by the Food and Drug Administration.

In both countries, there is a delineation between a food and a drug. Physiological claims, health claims can be made on drugs only after safety and efficacy approval. Health claims cannot be made on food. Some physiological claims are permitted on some foods, e.g., dietary fiber and the promotion of laxation.

U.S. NLEA and DSHEA

The Nutrition Labeling and Education Act (NLEA), passed in 1993, does not permit health claims for foods. Formally blocking products and product information from the market through the regulated channels of label, labeling and advertising forces information to reach the consumer through the unregulated channels of media. Nutrition and product information through this channel is often incomplete or erroneous. Less information, and less complete information, reaches the consumer under this format. (17)

Recently, the Food and Drug Administration took steps which positions them as followers to Japan in area of legislated health claims. In December 1994, a piece of legislation was passed in the U.S. which will permit health claims on certain dietary supplements with reference to the total diet. The Dietary Supplement and Health Education Act (DSHEA) creates a legal framework that allows manufacturers to make limited, sustainable claims about the health benefits of food supplements, and to present research results that support the claims. The new law also allows retail stores to provide third-party information on nutritional products, and the manufacturers of these products will be able to support their products through these channels. (41)

Like any legislation, says one author, this is a compromise (66). Nevertheless, it has achieved two major goals of the nutraceutical industry:

1. it has changed classification of supplements from food additives to "food"
2. supplements may now be labeled with truthful claims about the benefits for human health (66)

Canada *Food and Drugs Act and Regulations*

The purpose of the *Food & Drugs Act and Regulations* is to protect consumers from health hazard and fraud in the sale of foods, drugs, cosmetics and medical devices. (15)

A 'food': includes any article manufactured, sold or represented for use as food or drink for man, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.

A 'drug' includes any substance or mixture of substances manufactured, sold or represented for use in:

a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof, in man or animal,
b) restoring, correcting or modifying organic functions in man or animal....

Section 3 of the *Food and Drugs Act and Regulations* prevents health claims on food: "No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any disease, disorders or abnormal physical states referred to in Schedule A."

Schedule A includes alcoholism, arteriosclerosis, arthritis, asthma, cancer, diabetes, heart disease, hypertension, obesity, thrombotic and embolic disorders.

Dr. M. Cheney, Chief of the Nutrition Evaluation Division of the Health Protection Branch writes in regard to functional foods (15):

"In Canada, there are no specific regulations dealing with functional foods even though examples of such products have appeared on the Canadian market, such as:

- isotonic beverages for athletes
- grain products containing purified fiber ingredients
- fat substitutes based on modified starches
- proteins and vegetable gums
- eggs enriched with n-3 fatty acids
- herbs
- dairy products with bifidobacteria cultures

These foods are governed by the existing legislation and regulatory framework. Any claim for a product which involves prevention of a disease or modification or an organic function, for example, lowering serum cholesterol, is deemed to bring the product within the definition of a drug.

The rationale behind the prohibition is that the diseases in Schedule A require either medical diagnosis or treatment and the public should not be self-medicating for these diseases.

A novel fiber is defined as a food that is manufactured to be a source of dietary fiber and is "novel." Dietary fiber is an example of a food which is expected to be functional. The dietary fiber contribution of a novel fiber source may not be [declared] if both the safety and efficacy data have not been reviewed and found acceptable.

Experience with novel fibers suggests that there is a need to develop a policy framework regarding efficacy requirements for other functional foods carrying claims that might be considered suitable for foods and products declaring the presence of a 'nutraceutical' either added or occurring naturally.

In summary, the sale of "functional foods" or "nutraceuticals" as foods carrying overt physiological effect or health benefit claims on their labels is, at present, for the most part, not accommodated under current legislation in Canada. The questions, should there be health claims for foods, should new categories like "foods for special health purposes" be established for functional foods, and does the presence of an added nutraceutical constitute a claim in and of itself requiring proof of efficacy, will clearly need further consideration in Canada as they are certainly being debated in many other countries."

Future legislation: What can be expected and why

Dr. Childs (17) believes the major drivers in the American public policy arena appear to be the consumer's growing attention to diet, nutrition and health and the government's expanding commitment to nutrition education. These forces are contrasted by the FDA regulatory structure restricting marketing and health claims and the FDA's legal separation of food and drug.

Due to regulatory restrictions on health claims, it is suggested that some food companies communicate health messages the only way they can—through the media. As a result, the media is regarded as the best way to convince consumers of a product's health benefits; the medical community came in second. (16)

It is expected that legislation will become more lenient in regard to health claims on food products, since governments are facing an aging population and escalating health care costs. At the same time, legislators are coming to realize that a balanced diet would prevent many of the diet related diseases. (osteoporosis, obesity, tooth decay, blood pressure, anemia, etc.) (3)

Wrick (95) wrote reflectively on the role of regulations on food-based health claims. She has called for a professional debate on the following:

1. are there any untoward effects to those not at risk for breast cancer if they consume too much of the phytochemical?
2. if approved as a drug, would their (phytochemicals) cost increase and thereby availability to those unaware of having a high risk of breast cancer be reduced?
3. is the rigorous testing required, as for drugs, more appropriate from a public health and safety standpoint?

Brock (4) makes a strong appeal for supplementation of the American RDAs (Required Daily Amounts). ...The nutrition community should give serious consideration to the potential merits of nutrient supplements to fill the gap between the amounts of antioxidant nutrients found in typical diets and the higher levels needed for optimum protection against chronic diseases. As new knowledge of non-traditional, disease-preventing effects of micronutrients accumulates, new views on supplementation may be needed as well. The average American comes close to meeting the RDA of vitamin C and E, yet substantial segments of the population have much lower intakes of these important vitamins. However, effects on chronic disease prevention were

specifically excluded from consideration in the formulation of the RDAs. It is clear that substantial public health benefits could be achieved simply by ensuring that all Americans consume ample amounts of the antioxidant nutrients and the fruits and vegetables that contain them.

It becomes clear that a great opportunity to improve public health is seen by improving antioxidant nutriture. It is wise to advise people to eat more fruits and vegetables because:

1. there is little need for education because people consume the food already
2. people know they have reached a goal expressed in terms of servings rather than grams
3. the positive message of the campaign: people are told to eat something rather than eliminating something

A Canadian researcher echoed the same sentiment. "It is becoming apparent that there is a wide gap between the optimal intakes of n-3 PUFAs as required nutrients for essential neuronal and visual functioning and for the prevention and management of chronic disease, including cardiovascular disease. (38)

The food industry versus (or with) the pharmacy industry

Nutraceutical industry in the U.S.Childs study

As mentioned on numerous occasions in this report, a nutraceutical industry study was conducted in the U.S.. This study, by Dr. Nancy M. Childs, consisted of a mailed questionnaire, which was responded to by 96 leading food, pharmaceutical and biotechnology companies in the U.S.. (16)

The results indicated that 55% of food companies; 35% of pharmaceutical companies and 90% of biotechnology companies are now investing in nutraceuticals.

"The idea that foods can provide health benefits beyond week-to-week nutritional needs has captured the imagination of both the food and pharmaceutical industries." (64)

Functional food products are of interest to the food industry, however, they are also a category that is of interest to the pharmaceutical industry since their market segment is positioned at the food/pharma interface. (5)

Dr. DeFelice believes that the immediate potential for nutraceuticals is not in the supermarket, but in the "Over the Counter" (OTC) pharmaceutical market. (22)

Some believe infant formulae manufacturers are well-positioned to enter this market as they operate in the most regulated sector of the food industry. (16)

Clearly, the nutraceutical industry will be forged by both the food industry and the pharmaceutical industry. The specific role of each and the nature of the inevitable overlap remains to be defined.

Reasons for food industry involvement

"A growing number of food manufacturers are trying the proven strategy of fortifying foods with healthful ingredients. The trend of turning out foods that offer health benefits apart from regular nutritional needs also includes the pharmaceutical industry. (64)

NCI's research program into designer foods suggests a new industry—foods for disease prevention. It has the potential to be much larger than the vitamin industry and would offer consumers phytochemically enriched foods designed to prevent cancer and possibly other diseases as well. (12)

Dave Schwain, VP Marketing of Country Lake Foods: "Antioxidants are an emerging opportunity. We want consumers to use our juice and milk products for an expanding range of usage occasions. [...] The biggest challenge is still that there is little data on consumer consumption patterns of functional foods. (64)

Reasons for pharmaceutical industry involvement

The pharmaceutical industry is undergoing immense structural changes that result in major price and margin pressures. Generic competition is growing at a rapid rate. The OTC route was viewed with skepticism a few years ago, but has found enthusiastic endorsement with the discovery that the lower OTC price point is accompanied by phenomenally greater volume generation. Clearly, full consumer access to a product outperforms the gatekeeper pathway through the physician for the ethical product. (17)

Trends strongly suggest that the time is ripe for pharmaceutical firms to take a closer look at the potential opportunities in the nutraceutical market. (55)

To apply these observations to Canada, one must consider the readiness and current technological state of the pharmaceutical industry in Canada.

In response to the improvements in intellectual property rights, the PMAC (Pharmaceutical Manufacturers Association of Canada) made a commitment on behalf of its members to increase the percentage of sales spent on R&D in Canada from a 1985 benchmark of 4.95% of sales to 8% by 1991 and 10% by 1996. The greatest research growth is expected to occur in the area of age-related diseases, particularly those affecting the central nervous system and cardiovascular system. As part of its R&D efforts, the pharmaceutical industry in Canada is forming more links with university research groups and R&D intensive-biotechnology companies. (42)

Canadian demand for pharmaceutical products is expected to increase as a result of the aging of the population, more self-medication by consumers and the arrival of novel drugs on the market. Factors constraining industry growth include federal and provincial policies to contain health care costs, escalating costs of product R&D as well as the increasing time required for the introduction of new therapeutic agents. (42)

Ironically, what are viewed as factors constraining the growth of pharmaceuticals, are regarded as the very factors fostering a nutraceutical industry, e.g., containment of health-care costs, and the lower-cost R&D of a nutraceutical versus that of a pharmaceutical.

Market barriers

It was almost impossible for marketers or general business practitioners to realistically discuss the nutraceutical industry, without alluding to the impending market barriers. The most frequently mentioned market barriers and their authors are noted below:

- current regulatory environment preventing health claims on food (16, 64, 77, 86)
- cost of clinical trials (16, 22, 65)
- uncertainty to price (16)
- lack of harmony in regulations among the major markets of Canada, Japan and Western Europe (86)
- taste alone will reign supreme as the most powerful criterion. (77, 83)
- the concept of nutraceuticals is very broad and it means different things to different people, each of which can present different hurdles and consequences when it comes to government. (64)
- difficulty companies have in patenting a natural food component. This is critical before an individual food company spends the money to support the research needed to confirm a particular component's health benefit. (21, 23, 64, 77)
- inability to confidently establish market potential (77)

Distribution

The results of Childs' study (17) showed the preferred distribution "didn't wander from familiar territory": 86% of food companies said they are considering grocery stores; 67% of pharmaceutical companies are considering pharmacies and physicians' offices. Childs suggested that channel choices will vary by price points and degree of consumer interest in the category as a mass market or a niche specialty.

The relevance to Canada, should a nutraceutical category be legislated, is of high interest to legislators. There is a current high-profile debate between the Canadian Council of Grocery Distributors (CCGD) and the Canadian Drug Advisory Committee (CDAC) as to the appropriateness of selling OTC pharmaceuticals in grocery stores. The CCGD alleges that the pharmacists premium price by a factor of 8%. The CDAC claims that consumer safety is required, yet, they have been unable to substantiate the latter.

There may be, in Canada, an equal dispute over the distribution channels of nutraceuticals as there currently is over OTCs.

Requirements to grow a nutraceutical market

Functional foods have their own inherent problems in addition to the usual difficulties encountered in newly developed food products such as palatability and consumer acceptability. (38)

These problems are also requirements for a nutraceutical market. The literature search revealed the following issues to be considered:

Challenges for marketers at the food drug interface

- target those with the condition as well as those concerned about developing the condition
- target the audience of people with the diagnosed condition and the health professionals who work with them
- don't anger the physicians by targeting a diverse audience who could never benefit from consumption of your product
- retention of bioavailability is very important and crucial to food being the carrier of the active ingredient/compound
- opportunities which represent strong proprietary positions which can justify the cost of clinical testing and consumer education

(from 95)

Challenges of the "designer food" industry

- we need multifunctional ingredients to be economically viable
- there is the question of nutrient density
- micronutrient (antioxidants, preservatives, vitamins, minerals) balance
- therapeutic value of nutrients
- food and drug interactions
- drug-induced nutritional deficiencies
- cost-effective production, distribution, and marketing

(from 79)

Requirements for a nutraceutical industry

- collaboration between food and pharmaceutical companies
- some mechanism by the FDA that would "incentivitize" research expenditures by food and pharmaceutical companies in the area of nutraceuticals
- close cooperation among research representatives in industry, government and academia (that is almost a given)

(from 76)

What needs to be done

- stick to our track record of food safety—don't depart from that
- establish active ingredients—ensure the bioactivity is stable
- capture the essence of unmet market needs. Consumers are not aware of the need. Nutraceuticals are visionary as were Sony Walkmans and Post-it Notes. The market requires nutritionally aware consumers.
- communicate the benefit and proof of the benefit to targeted consumers

(from 38)

Market size

Pitts (69) writes that "we" don't know the potential of the market and some of the estimates published differ significantly from each other. He claims there is an important market and it is

growing apace as all developed countries are facing an aging population. Consequently, pharmaceutical drug use increases significantly with age. The author quotes Furikawa (35) as predicting that the international nutraceutical market could grow from US$ 8 B to US$ 500 B by the year 2010. No supporting data was included with this estimate.

Childs (17) admits that market size is a deceptive concept. Market size can be realized in terms of both volume and sales dollars. In terms of volume, there are mass market needs, however, there will be niche market solutions. These health specific, disease specific categories will require careful target marketing and target product development. Sales dollars are dependent on pricing, which will vary by industry. The pharmaceutical industry, for example, will demand higher price points due to its higher internal ROI structure.

Sales dollars

Tomomatsu (89) pegs the Japanese market at US $4.5 B growing to US $6 B by 1995. The same article value the American nutraceutical market at US $2.5 B in 1988 to US $ 9 B in 1995.

One author draws a close relationship between the value and rate of growth of the nutraceutical industry, and, FDA regulations. (14). Without health claims, the U.S. market is predicted to grow slowly at 2.4% annually, to a total value of US $1.22 B in 1998. With health claims, the U.S. market is predicted to grow faster at 9% annually, to a total value of US $1.66 billion in 1998.

One can postulate then, by assigning a 10% magnitude factor to the Canadian population. Using the same variable of regulatory climate, the Canadian nutraceutical market, in 1998, would range from US $ 100 million to US $ 160 million.

Sales volume

Childs' study (16) surveyed the specific diseases targeted by the firms in her research. Fifty to seventy percent of the U.S. firms were targeting diseases such as coronary heart disease, cancer and hypercholesterolemia. More than 33 % of the group were targeting osteoporosis and diabetes. Additional responses included immunology, infant formula, asthma, and weight reduction.

This information suggests the need for target marketing, and selecting an unmet need which fits with the company's strengths.

Nutraceuticals, while offering health benefits to consumers, are only one piece of an overall healthful-living picture. The public should decrease fat consumption and increase fiber consumption and therefore companies should maintain key fat-reduction and fiber-based research projects. Despite this basic requirement, the market for nutraceuticals in the U.S. will be significant. (33)

Mullich (62) quotes Stokely USA as having conducted focus groups and monitored the consumer press to determine which nutrients had seeped into the nation's collective conscience. "You don't just guess", he added.

Thus, the size of the market, in volume terms, depends on, firstly, agreed upon definition. If a nutraceutical is to prevent or treat a targeted disease, then in volume terms, the volume of the

nutraceutical can be estimated by knowing both the amount of the afflicted population, and the effective dose requirements. Market size in terms of sales dollars, however, depends on a company's pricing strategy and what price the market is willing to bear.

Until actual relationships between dose requirements of nutrients and effectiveness are established, only market volume can be estimated. This estimate depends on product definition and prevalence of the targeted disease.

Determinants of the nutraceutical industry

Many of the authors writing on the subject of nutraceuticals offered their perspectives on what forces, trends and advances will facilitate the evolution of this industry. Excerpts from the literature are provided below.

King Communications (49a) cites a research paper quoting the following influences on the nutraceutical industry:

- regulatory environment
- consumer acceptance
- competition for other "healthy" foods and diet supplements (may impact negatively)
- the extent to which marketers work to develop the nutraceutical market. It is overseas that marketers are learning to market nutraceutical. When the US regulatory atmosphere changes, American companies that competed abroad will be prepared to compete at home.

Quoting Peter Allen of FIND/SVP, "Oddly enough, one of the main growth factors for nutraceuticals, the fact that Americans are eating healthier and more health foods, will also be one of the barriers for nutraceuticals. Nutraceuticals compete with the same market that helps them grow. The trick is to differentiate the nutraceuticals from health foods."

Pierson (68) states that health care costs exceed US $800 B. This factor alone suggests it is prudent to focus on preventive measures that are controllable in our lifestyles.

Advanced technology strongly suggests that our food supply can be made much more healthier and rationally preventive.

DeFelice (23) cites the following determinants:

- consumer and physician product awareness
- unique, flexible company management
- small entrepreneurial units The market fits neither the consumer OTC culture or the ethical pharmaceutical culture; while the pharmaceutical industry lacks the will, they have the knowledge; the food industry has the will, but lacks the expertise.

Schmidl (73) cites a number of determinants:

- scientists with an understanding of food systems and clinical nutrition will help create better quality and more stable products
- better clinical evidence relating specific dietary components to health and disease

- a pervasive but necessary regulatory climate allowing proper and valid claims to be made about the healthfulness of specific foods
- willingness of companies to invest in the area where the population at risk is limited but the moral and ethical obligations of society are high
- state governments and the insurance industry to recognize that these new special medical foods. Small populations may need insurance coverage to cover the high price of low volume. This in turn would stimulate development and manufacture by the food and pharmaceutical industries.

Wrick (95) quotes the following forces as shaping and/or sustaining the food-drug interface:

- nutritional epidemiology must be further researched. Still, consumers and even some health professionals are ready to make a causative link in their own minds.
- consumer interest in diet and health has lead to changes in life-style and food purchasing patterns.
- distribution changes and trends e.g., prescription medicines switch to OTC status and more OTC medications are distributed through supermarket health and beauty aid sections.
- the high cost of treating chronic diseases that might reasonably be reduced in severity or even prevented by changing behavior earlier in life
- consumers turning to alternative and non-traditional forms of medical therapy when they feel the current system does not adequately address their needs

Writing on the European situation, a number of influential factors were cited (32):

- consumer trends as consumers are looking for positive health benefits not just products which are less harmful
- market development which is dependent on the extent and nature of consumer awareness and credibility of health enhancing ingredients
- regulatory issues; as regulators are now taking a more positive attitude, soon some claims will be possible. These claims should be carefully monitored. Market growth will depend upon the amount of substantiating evidence which can be provided
- more research—growth in the research programs designed to clarify the therapeutic value of the ingredients will increase
- government's pursuit to reduce or curb the costs of health care thus providing further support to these research programs
- ingredient/products—key: identify those ingredients and products which are credible to the consumer, satisfy a real consumer need, and which can provide sustained competitive advantage
- technologies which enable the cost effective extraction, purification and incorporation of such ingredients into food
- Japanese development not only continues to influence Japan, but also applies to many developed western countries

Bontenbal (5) cites the following determinants:

- a growing understanding of dietary components

- the larger social trend towards self-medication, disease prevention and increased awareness of the relationship between diet and health
- consumer loyalty and a sustainable market when the relationship between health and the ingredient is beyond doubt

Childs (16) predicts market will open up mainly because of:

- demographic and health-care trends
- more absorption of health-care costs by consumers which gives them the financial incentive to take control of their health
- the rise of health management centers which preaches and permits preventive medicine
- a pharmaceutical industry which is much more financially creative with its strategic alliances and joint ventures than the traditional food industry

Childs (17), looking ahead to the 21st century, recognizes four broad trends:

- a convergence among nutritional, pharmaceutical and food science domains
- a merging of consumer and professionally-indicated products
- the blending of clinical and epidemiological documentation to demonstrate significant scientific agreement
- gradual repositioning of federal agency roles and functions as the FDA continues to expand its role in nutrition and public health education

The Keystone Center (48) cites three forces behind the nutraceutical industry:

- the advancement of science to demonstrate health benefits from one's diet from food primarily consumed for pleasure and nutrition
- consumers enthusiastic interest in informing themselves of the foods they eat as part of an overall effort to improve their health
- escalating costs of health have prompted a critical reassessment of the role of prevention efforts to improve health as a means of reducing national health costs

Stillwill (86) quotes studies which link nutrients to health, combined with the social trend that people are taking greater control over their own health, are driving food processors to help consumers meet their health goals. It is important, he adds, to realize that this is an international phenomena.

A report in Industrial Bioprocessing envisions both the food industry and pharmaceutical industry clamoring for shelf space in a number of retail outlets. (41)

"Companies introducing food products that offer specific health benefits will create heavy competition for traditional food companies, and will quickly capture market share from OTC pharmaceutical manufacturers. Companies that manufacture nutritional ingredients—and this includes bioprocessing firms—will experience an upturn in demand as food manufacturers see benefit from using those ingredients. Grocery stores will face a growing demand for nutritionally enhanced foods, and for the information resources that accompany them. Consumers will expect

pharmacy retailers to sell not only traditional OTC pharmaceuticals but also the nutraceutical foods that offer the same benefits."

Wrage (94) quotes the impact of the DSHEA in the U.S. and its effect on both the pharmaceutical and food industries. "Once entrepreneurial companies recognize the implications of the act, they will begin to develop patented nutraceuticals, clinically evaluate them and market them within a very short period of time, competing at the marketplace with pharmaceutical and food products."

The three most prominent forces appear to be escalating health care costs (which is closely tied in with a switch to non-traditional or alternative medicines), a growing awareness, among both consumers and physicians of the relationship between nutrient intake and disease(s), and regulatory approval of health claims.

Strategic alliances

As O'Donnell (64) quotes, strategic alliances are already beginning to happen. Celestial Seasonings recently signed a letter of intent to license its name to Warner-Lambert (Listerine, Halls Cough Drops). Sandoz's recent purchase of Gerber Products "signaled the kind of alliances between food and drug companies that would advance nutraceuticals."

Pitts (69) notes that "already a number of joint ventures have occurred between dairy and pharmaceutical companies, which may result in a later stage in the launch of functional foods. The French seem to be most active in such ventures.

DeFelice (23) outlined the strengths and weaknesses of the food and pharmaceutical industries with respect to nutraceuticals. (See Determinants above).

Childs (17) comments on the "role of other players". "food ingredient suppliers, biotech ventures, international participants, herbal manufacturers and nutritional supplement manufacturers are potential participants in the category, either directly or indirectly, through alliances and partnerships.

Although the most ideal strategic alliance is yet to be defined, one can learn from the constituents of current alliances as to what each partner is gaining and contributing in the arrangement. As observed by O'Donnell, the most probably appears to be a food company and pharmaceutical company joining forces.

Consumer acceptance studies

Wrick (95, 96) has conducted an American consumer study on the topic of designer foods. Her results showed the following:

- American adults over the age of 18 were at least somewhat aware (30% considered themselves highly aware) of the research activities linking disease prevention and naturally occurring substances in fruits and vegetables and cereal grains
- awareness increased with age
- awareness showed no significant differences due to income, educational level, race, occupational status or geographical region

- the most appealing method to increase consumption was to increase the daily consumption of fruits and vegetables and cereal products
- this was followed by developing special varieties of these foodstuffs to contain greater amounts of such substances.
- the third most preferred approach was to add them to basic foods such as bread or flour
- the concept of a designer food, created to help those at risk for certain chronic diseases, appears to be an idea whose time has come

Sloan (83) wrote an article in the July 1994 issue of Food Technology entitled "Top Ten Trends to Watch and Work On". The number one trend was " Kitchen Cabinet vs Medicine Cabinet". (Although I read the original, this article has been passed onto me by at least four Canadians. The article, author and publication all have high credibility).

The main points in Sloan's article are the following:

- kitchen cabinet is deemed to offer more desirable health solutions than the medicine cabinet
- of Americans have changed their eating habits to specifically address heart disease, hypertension, cholesterol or obesity. A drop in blood cholesterol levels and decreased fat consumption is hard evidence that preventive nutrition has quietly crossed into mainstream behavior
- tomorrow's consumers will seek to include health-promoting ingredients in their diets such as the antioxidant vitamins, fiber, calcium, folic acid, flavonoids and other phytochemicals—whether approved for health claims by FDA or not.
- Miles Laboratories' decision to include garlic in their "one-a-day" vitamin supplement demonstrates the strength of this new frontier
- with the recent emphasis on phytochemicals and their health-promoting effects, there is growing debate as to whether there will be a gradual shift to consumers seeking more of their vitamins from food, particularly fortified foods. Not only would they get the necessary nutrients they require from food, but they would automatically obtain additional health benefits from the other non-vitamin components.

In Europe, a recent in-depth consumer and market report on functional foods indicated that 70% of German respondents, 68% of UK respondents and 55% of French respondents thought that diet was the most important factor in determining health. In some categories of functional foods, German respondents indicated that they were twice as likely to have bought functional foods than their European neighbors. (32) However, different definitions operate in each country. (*This, as cited earlier, can prevent the evolution of nutraceuticals)*. Therefore, the markets across Europe are somewhat fragmented and knowledge of consumer attitudes towards functional foods is even more restricted.

Gasparello (36) postulates that nutraceuticals have gone [further] in the international market for a number of reasons:

- older demographics
- an acceptance of the food to health relationship

- cultures which value herbal and natural remedies (those cultures also permit health claims, reimbursement is common and nutrition is part of the medical curriculum)
- national health-care

Benefits of nutraceutical industry

While the reviewed papers referred to the characteristics, requirements and dynamics of the nutraceutical industry, only one, a Canadian succinctly stated benefits. The four proposed by P. Wood (93) include:

- reduced health care costs and improved well-being of Canadians
- competition readiness and domestic and export opportunities for the Canadian food industry
- improved understanding and public awareness of diet-health relationships
- new value-added processing for Canadian crops

Developing business in this area is not easy, but for those who approach the challenges with the right skills and resources, and who have an integrated approach to development, the commercial potential is considerable. (10)

Appendix 2: Bibliography

The following list of references is, in-part, intended to illustrate the spectrum of information being published on the subject of nutraceuticals. The range of sources is thus very broad, including newspapers, popular magazines, bulletins, trade publications, books and scientific journals.

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